

**EPA Reg. No. 81598-12**  
**Vol. 1**





## Adeeb, Shanta

---

**From:** James Wagner <jmw@wagnerreg.com>  
**Sent:** Tuesday, February 09, 2016 2:14 PM *Resubmission #1*  
**To:** Adeeb, Shanta  
**Subject:** FW: Response to Agency letter for EPA Reg. No. 81598-12  
**Attachments:** Basic CSF 1-25-2016.pdf

**Follow Up Flag:** Follow up  
**Flag Status:** Flagged

Hi Shanta,

I have revised the Basic CSF attached to list all of the dioxins and furans.

Best regards,

Jim Wagner  
Regulatory Consultant  
Tel: (302) 635-7290  
Mobile: (302) 530-5745

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**From:** James Wagner  
**Sent:** Monday, February 08, 2016 11:21 AM  
**To:** 'Adeeb, Shanta' <Adeeb.Shanta@epa.gov>  
**Subject:** RE: Response to Agency letter for EPA Reg. No. 81598-12

Hi Shanta,

I will revised the CSFs today and email them to you.

Thanks,

Jim Wagner  
Regulatory Consultant  
Tel: (302) 635-7290  
Mobile: (302) 530-5745

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**From:** Adeeb, Shanta [mailto:Adeeb.Shanta@epa.gov]  
**Sent:** Monday, February 08, 2016 11:00 AM  
**To:** James Wagner <jmw@wagnerreg.com>  
**Subject:** Response to Agency letter for EPA Reg. No. 81598-12

Good Morning Jim,

I just received the CSFs you submitted in response to the Agency Letter dated July 31, 2015. The Basic CSF you submitted needs to list all the dioxins and furans like was done for Alternate CSFs #1 and #2. No additional work will be done on this action until the revised Basic CSF has been received. Feel free to contact me if you have any questions.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

February 3, 2016

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

MS. CARRIE NOLAN  
WAGNER REGULATORY ASSOCIATES, INC.  
ROTAM LIMITED  
7217 LANCASTER PIKE, SUITE A, PO Box 640  
HOCKESSIN, DE 19707-

PRODUCT NAME: ROTAM DICAMBA TECHNICAL  
COMPANY NAME: ROTAM LIMITED  
OPP IDENTIFICATION NUMBER:  
EPA FILE SYMBOL: 81598-12  
EPA RECEIPT DATE: 01/25/16

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 23, at (703) 305-1243.

Sincerely,

A handwritten signature in black ink, appearing to be "S. [unclear]".

Front End Processing Staff  
Information Services Branch  
Information Technology & Resources Management Division



## Fee for Service

{980318.~

This package includes the following

☐ New Registration

☒ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: \_\_\_\_

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr. 23

Receipt No.

S-

980318

EPA File Symbol/Reg. No.

81598-12

Pin-Punch Date:

1/25/2016



This item is NOT subject to FFS action.

### Action Code:

Requested:

Granted:

Amount Due: \$ \_\_\_\_\_

### Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: J. GARVINE

Date: 2/2/14

Remarks:

key - if PRIA, please return to state

DOCUMENTUM

# FAST-TRACK AMENDMENTS – Completeness Screening Checklist

Expert's In-Processing Signature: L. Patel

Date: 1/24/16 PM #: 23

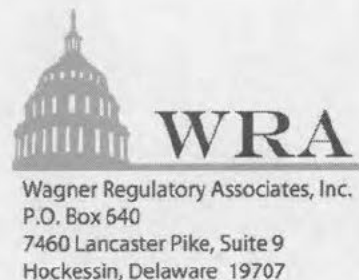
EPA Reg. Number: <u>81598-12</u>		EPA Receipt Date: <u>1/25/16</u>		
	Checklist Item	Yes	No	N/A
1	<b>Application Form</b> (EPA Form 8570-1) - signed?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	<b>Confidential Statement of Formula</b> (EPA Form 8570-29) - signed?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	<b>Certification with Respect to Citation of Data</b> (EPA Form 8570-34) - signed?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
4	<b>Formulator's Exemption Statement</b> (EPA Form 8570-27) - signed?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
5	<b>Data Matrix</b> (EPA Form 8570-35) [Applicable for adding me-too uses] - signed?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	a) Selective Method?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	b) Cite-All Method?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	c) Public copy of Matrix provided? See PR Notice 98-5	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6	<b>Is Label included?</b> (5 copies)	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
	a) Electronic Label submitted?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Comments:</b>          				



ELECTRONIC SUBMISSION

January 25, 2016

Document Processing Desk  
ATTN: Kathryn Montague, PM Team 23  
Registration Division (7504P)  
U.S. Environmental Protection Agency  
Office of Pesticide Programs  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501



Dear Ms. Montague:

**Re: Rotam Dicamba Technical, EPA Reg. No. 81598-12**  
**Response to Agency Initiated Action dated July 31, 2015**

I am responding to your letter referenced above requesting the submission of dioxin and furan analytical data by January 31, 2016, for the technical source listed in the Basic CSF of 9/6/2011.

We discussed this by email in October and reached agreement on an alternate way to address this matter by eliminating the source of technical [REDACTED] that lacks the noted analytical data and by submitting revised CSFs as a non-PRIA amendment. Accordingly I have revised the currently approved CSFs as shown in the table below.

CSF Formulation	Date of CSF	Source of Technical	Revision
Basic	9/6/2011	[REDACTED]	This source is eliminated.
Alternate #1	12/04/2014		Changed to "Basic" formulation with CSF date of 1/25/2016.
Alternate #2	11/15/2014		Changed to "Alternate #1" with CSF date of 1/25/2016.
Alternate #3	1/19/2015		Changed to "Alternate #2" with CSF date of 1/25/2016.

To support this request I have enclosed the following documents:

- Agent letter for Rotam, Ltd.
- Agency letter of July 31, 2015.
- Email chain from October 7, 2015.
- Agency approval letters for Alternate # 1-3 CSFs
- Application for amendment
- New, revised CSFs – Basic, Alternate #1 and Alternate #2.

Please contact me via email at james@wagnerreg.com or telephone at (302) 635-7290 if you have any questions.

Respectfully submitted,

James M. Wagner  
Agent for Rotam Limited  
Enclosures

DOCUMENTUM

		United States <b>Environmental Protection Agency</b> Washington, DC 20460		<div style="border: 1px solid black; padding: 2px; width: 30px; margin: 0 auto;">X</div>	<b>Registration</b>  <b>Amendment</b>  <b>Other</b>	OPP Identifier Number
<b>Application for Pesticide - Section I</b>						
1. Company/Product Number 81598-12		2. EPA Product Manager Kathryn Montague		3. Proposed Classification  <div style="display: flex; justify-content: space-between;"> <span><input checked="" type="checkbox"/> None</span> <span>Restricted</span> </div>		
4. Company/Product (Name) Rotam Limited / Rotam Dicamba Technical		PM# Product Manager Team 23				
5. Name and Address of Applicant (Include Zip Code)  Rotam Limited c/o Wagner Regulatory Associates, Inc. P.O. Box 640 Hockessin, DE 19707  <input type="checkbox"/> Check if this is a new address		6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. Product Name:				
<b>Section - II</b>						
<div style="display: flex; flex-wrap: wrap;"> <div style="width: 50%;"> <input checked="" type="checkbox"/> Amendment - Explain below.         </div> <div style="width: 50%;"> <input type="checkbox"/> Final printed labels in response to Agency letter dated _____         </div> <div style="width: 50%;"> <input type="checkbox"/> Resubmission in response to Agency letter dated _____         </div> <div style="width: 50%;"> <input type="checkbox"/> "Me Too" Application.         </div> <div style="width: 50%;"> <input type="checkbox"/> Notification - Explain below.         </div> <div style="width: 50%;"> <input type="checkbox"/> Other - Explain below.         </div> </div>						
<b>Explanation:</b> Use additional page(s) if necessary. (For Section I and Section II.)						
<b>ELECTRONIC SUBMISSION - Non-PRIA CSF amendment. See cover letter.</b>						
<b>Section - III</b>						
<b>1. Material This Product Will Be Packaged In:</b>						
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No		Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No  If "Yes"      No. per Unit Packaging wgt.      container		Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No  If "Yes"      No. per Package wgt      container		2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) HDPE lined bags
<b>* Certification must be submitted</b>						
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container Bulk		5. Location of Label Directions <input type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product		
6. Manner in Which Label is Affixed to Product <div style="display: flex; align-items: center;"> <input type="checkbox"/> Lithograph         <input checked="" type="checkbox"/> Paper glued         <input type="checkbox"/> Stenciled         <input type="checkbox"/> Other _____       </div>						
<b>Section - IV</b>						
<b>1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)</b>						
Name James Wagner		Title Agent for Rotam Limited		Telephone No. (Include Area Code) (302) 635-7290		
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.						6. Date Application Received  <div style="text-align: center; border: 1px solid black; padding: 5px;"> <b>(Stamped)</b> </div>
2. Signature  		3. Title Agent for Rotam Limited				
4. Typed Name James M. Wagner		5. Date January 25, 2016				

# PROCESSING REQUEST

Reg # 81598-12

Decision #499330

Description: PRIA R351 CSF Amendment

**Electronic Label & Letter**  
(see PPLS):

OR

**Non Electronic  
Label & Letter**  
(Scanning required):

☐ Dated:

☐ Dated:

\*\*\*Only one label type should be selected\*\*\*

**Other Materials Sent** (see jacket):

☒ New CSF(s) Dated: 1/19/15 Alt 3

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

**Reviewer: Deirdre Sunderland**

**Division: RD**

**Phone: 703.603.0851**

**Date: 8/21/15**





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

August 19, 2015

James Wagner  
Agent  
Rotam Limited  
c/o Wagner Regulatory Associates, Inc.  
P.O.Box 640  
Hockessin, DE 19707

Subject: PRIA CSF Amendment – Adding new unregistered source of active ingredient to  
Alternate CSF #3  
Product Name: Rotam Dicamba Technical  
EPA Registration Number: 81598-12  
Application Date: January 19, 2015  
Decision Number: 499330

Dear Mr. Wagner:

The Confidential Statement of Formula (CSF) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 9/6/2011
- Alternate CSF 1 dated 12/4/2014
- Alternate CSF 2 dated 11/15/2014
- Alternate CSF 3 dated 1/19/2015

Any CSFs other than those listed above are superseded/no longer valid. If you have any questions, please contact Deirdre Sunderland by phone at (703)603-0851, or via email at [sunderland.deirdre@epa.gov](mailto:sunderland.deirdre@epa.gov).

Sincerely,

A handwritten signature in cursive script that reads "Kathryn V. Montague".

Kathryn V. Montague, Product Manager 23  
Herbicide Branch  
Registration Division (7505P)  
Office of Pesticide Programs





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS  
REGISTRATION DIVISION (7505P)

**FEE**

**DOCUMENT CONTAINS CONFIDENTIAL INFORMATION**

DP BARCODE: 425680; DECISION NO.: 399330; Reg. No. No.:81598-12

PRODUCT NAME: Rotam Dicamba Technical: PC CODE(s): 029801;

DATE: July 8, 2015

SUBJECT: Product Chemistry Review of Rotam Dicamba Technical

FROM: Akiva Abramovitch, Ph.D.  
CITAB / RD (7505P)

*[Handwritten signature]*

THROUGH: Shyam Mathur, Ph.D.  
Product Chemistry Team Leader  
CITAB /RD (7505P)

*[Handwritten signature] 7-13-2015*

TO: Deirdre Sunderland / Kathryn Montague PM 23  
Herbicide Branch / Registration Division (7505P)

REGISTRANT: Rotam Limited  
MRID Numbers: 495495-01 to -04

**INTRODUCTION:**

Rotam Limited is proposing amendment to add a new manufacturing site of active ingredient in [REDACTED] for Rotam Dicamba Technical listed on Alternate CSF #3 dated January 19, 2015. The applicant submitted product Chemistry Guideline reference 830 subgroup A & B data. CITAB has been asked to determine the acceptability of the product chemistry data and the aforementioned alternate formulation CSF.

**SUMMARY OF FINDINGS:**

1. Group A guidelines: (product identity & composition).

The active ingredient was adequately described (MRID #495495-01) in Alternate CSF dated January 19, 2015. The nominal concentration of the active ingredient proposed on the Alternate CSF #3 averaged 97.3% which is within certified limit on the currently approved basic CSF dated September 6, 2011 and the product label claim of 98.9%.

830.1600 (description of materials used to produce the product)

The registrant has listed satisfactorily the starting materials used at the alternate production site and the relevant data are included in (MRID #495495-01).

830.1620 (description of production process)

The relevant data are included in (MRID #495495-01) and is acceptable.

830.1670 (discussion on the formation of impurities)

The nominal concentrations proposed for impurities are the averages derived from the five batch analysis (#495495-03) was provided. According to the Alternate CSF, the product manufactured at the alternate sites does not contain any new impurities of significant toxicological concern. The remaining impurities of significant toxicological concern (Polychlorinated Dibenzodioxins and polychlorinated Dibenzofurans) were analyzed and were determined to be below the level of concern.

830.1700 (preliminary analysis)

The submitted data are acceptable. Results are presented for a five-batch analysis of the active ingredient (MRID #495495-02 and 03) was determined by HPLC/ UV Detector using external standard for analyses. The dioxin and dibenzofuran analyses were performed by high resolution GLC/MS

830.1800 (enforcement analytical method)

The active ingredient was analyzed by HPLC/ UV Detector using external standard for analyses, Acetonitrile was used as a solvent. (MRID#495495-02). The information presented meets the data requirements for 40 CFR 158.355

2. Group B guidelines (physical-chemical properties):

Data submitted in MRID 495495-04 but will not be reviewed since the data was already submitted for the Basic CSF.

**DP BARCODE: 425680; DECISION NO.: 399330; Reg. No. No.:81598-12**  
**PRODUCT NAME: Rotam Dicamba Technical: PC CODE(s): 029801;**

**CONCLUSIONS:**

The CITAB has reviewed the product chemistry data submitted to support the proposed alternate CSF #3 for "Rotam Dicamba Technical" and has concluded that:

1. The data submitted for guidelines 830.1700 (preliminary analysis) and 830.1800 (enforcement analytical method) and all relevant production data provided for the alternate production site are included in summary of findings and are acceptable.
2. Impurities of significant toxicological concern were adequately analyzed and listed on the Alternate CSF#3 dated January 19, 2015. Analytical data were submitted to indicate that the impurities of significant toxicological concern (Polychlorinated Dibenzodioxins and polychlorinated Dibenzofurans) were below the level of concern. The data submitted are acceptable.
3. The proposed alternate CSF #3 dated January 19, 2015 is acceptable. The lower and upper certified limits for the A.I. are within EPA's Standard Certified Limits set on the basic CSF







UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460  
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION  
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

**DP BARCODE No.:** D425680; **FILE SYMBOL No.:** 81598-12 alt CSF #3 (screen); **PRODUCT NAME:** Rotam Dicamba Technical; **DECISION No.:** 499330; **PC Code(s):** 029801; **ACTION CODE:** R351; **FOOD Use:** Yes

**DATE OUT:** March 2, 2015

**SUBJECT:** Completeness check screening for end use product "Rotam Dicamba Technical"

**FROM:** Shyam Mathur,  
Product Chemistry Team Leader  
CITAB/RD (7505P)

**TO:** Deirdre Sunderland / Kathryn Montague, RM 23  
Herbicide Branch / RD (7505P)

**Company Name:** Rotam Limited  
**Formulation Type:** Herbicide  
**Active Ingredient(s):** Dicamba (97.3%)  
**MRID No(s):** 49549501 to 49549504

**Deficiencies:** No  
(if there are deficiencies they are indicated below each heading as Note 1, Note 2 Etc).

**CONCLUSION:**

**Group A:** Data submitted

**Group B:** Data not required

**CSF:** Alternate CSF #3 (dated 01-19-2015) submitted.

**Product label:** Not Submitted

Note to PM: If the deficiencies are found in the screen results, please inform the registrant and bring back to me or to Joe the corrected deficiencies in response to 10 day letter, so that it can be attached to the original bean, if the data package is still in CITAB. New Bean is required in case the bean has been closed by CITAB. Thank you.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

January 26, 2015

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OPP Decision Number: D-499330  
EPA File Symbol or Registration Number: 81598-12  
Product Name: ROTAM DICAMBA TECHNICAL  
EPA Receipt Date: 22-Jan-2015  
EPA Company Number: 81598  
Company Name: ROTAM LIMITED

JAMES WAGNER  
WAGNER REGULATORY ASSOCIATES, INC.  
ROTAM LIMITED  
PO Box 640  
HOCKESSIN, DE 19707-

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R351

AMENDMENT; UNREGISTERED SOURCE OF ACTIVE INGREDIENT;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 347-8961.

Sincerely,

A handwritten signature in black ink, appearing to be "m jha", is written over the word "Sincerely,".

Front End Processing Staff  
Information Technology & Resources Management Division

**Fee for Service**

{963217}~

This package includes the following

☐ New Registration

☒ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: \_\_\_\_\_

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr. 23

Receipt No.

S- 963217

EPA File Symbol/Reg. No.

81598-12

Pin-Punch Date:

1/22/2015

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R351

Granted: R351

Amount Due: \$ 12,596

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Maggie Rudick Date: 1/23/15

Remarks: add source of A.I. to technical product

# Receipt for Section 3

S: 963217

Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☐ Yes ☒ No

Application Type: Amendment

Fee For Service: ☐ Yes ☒ No

Billable: ☒ Yes ☐ No

Company: 81598 ROTAM LIMITED

V

Print Letter

Enter More Information

Tracking

Risk Manager: Registration Division, Risk Management Team 23

Product #: 81598-12

Product Name: ROTAM DICAMBA TECHNICAL

Override#:

Me Too

Me Too Product

Section3:

Name:

Application Date: 19-Jan-2015

OPP Rec'd Date: 22-Jan-2015

Front End Date: 22-Jan-2015

Risk Manager Send Date:

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

AMENDMENT WITH STUDIES

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

Receipt Content

Study

CSF

View/Edit

\*Product ingredient source information may be entitled to confidential treatment\*



# PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 1-22-15

Experts In-Processing Signature: B.B.

Date 1-26-15

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date \_\_\_\_\_

EPA Reg. Number: <u>81598-12</u>		EPA Receipt Date: <u>1-22-15</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A) <i>No inerts to review</i>	yes	no			
		X				
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
		X				
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of <u>Label</u> (Electronic labels on CD are encouraged and guidance is available)					X
7	Is the data package consistent with PR Notice 86-5			X		
8	Notice of Filing included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
10	<u>Required Data</u> and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

\* Documentation: PASS / FAIL

• required forms are complete

\* Inerts: PASS / FAIL

• Technical & Impurities only. No Inerts to review

\* PRN 11-3: PASS / FAIL

MRID: 495495

\* Overall Status: PASS / FAIL

X

1-28-15

## Cheryl Wagner

---

**From:** notification@pay.gov  
**Sent:** Tuesday, January 20, 2015 4:44 PM  
**To:** Cheryl Wagner  
**Subject:** Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or [yanchulis.michael@epa.gov](mailto:yanchulis.michael@epa.gov).

Application Name: PRIA Service Fees  
Pay.gov Tracking ID: 25JDGP52  
Agency Tracking ID: 74740082210  
Transaction Type: Sale  
Transaction Date: 01/20/2015 04:43:49 PM EST

Account Holder Name: Cheryl R. Wagner

Transaction Amount: \$12,596.00  
Billing Address: 7217 Lancaster Pike  
Billing Address 2: Suite A  
City: Hockessin  
State/Province: DE  
Zip/Postal Code: 19707  
Country: USA  
Card Type: AmericanExpress  
Card Number: \*\*\*\*\*2008

Registration Number: 81598-12  
Company Name: Rotam Limited  
Company Number: 81598  
Action Code: R351

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.





## Receipt

### Your payment is complete

Pay.gov Tracking ID: 25JDGP52

Agency Tracking ID: 74740082210

Form Name: Pesticide Registration Improvement Act - Prepayment

Application Name: PRIA Service Fees

### Payment Information

Payment Type: Debit or credit card

Payment Amount: \$12,596.00

Transaction Date: 01/20/2015 04:43:49 PM EST

Payment Date: 01/20/2015

Registration Number: 81598-12

Company Name: Rotam Limited

Company Number: 81598

Action Code: R351

### Account Information

Card Holder Name: Cheryl R. Wagner

Billing Address: 7217 Lancaster Pike

Billing Address 2: Suite A

City: Hockessin

Country: United States

State/Province: DE

ZIP/Postal Code: 19707

Card Type: American Express

Card Number: \*\*\*\*\*2008

### Email Confirmation Receipt

Confirmation Receipts have been emailed to:

cheryl@wagnerreg.com

carrie@wagnerreg.com





January 19, 2015

Document Processing Desk (REGFEE)  
ATTN: Kathryn Montague, PM Team 23  
Registration Division (7504P)  
U.S. Environmental Protection Agency  
Office of Pesticide Programs  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501



**WRA**

Wagner Regulatory Associates, Inc.  
P.O. Box 640  
7217 Lancaster Pike, Suite A  
Hockessin, Delaware 19707

Dear Ms. Montague:

**Re: Rotam Dicamba Technical, EPA Reg. No. 81598-12**  
**PRIA Category R351: Amendment to Add a New Source of Active Ingredient**

Wagner Regulatory Associates, Inc., on behalf of Rotam Limited, respectfully submits the following documents in order to amend the existing registration to add an additional source for technical grade active ingredient:

- Letter from Rotam Limited appointing Wagner Regulatory Associates, Inc. as its agent
- Application for Pesticide Amendment (8570-1)
- Confidential Statement of Formula (8570-4), 2 copies
- Certification with Respect to Citation of Data (8570-34)
- Data Matrix (8570-35)
- Data Transmittal Document
- 3 copies of data as outlined in the Data Transmittal Document
- Receipt for payment of PRIA fee

For the determination of the PRIA registration service fee, this application qualifies as EPA category R351, fee \$12,596. The fee has been paid through [www.pay.gov](http://www.pay.gov) and a copy of the payment receipt is attached.

Please feel free to contact me via email at [james@wagnerreg.com](mailto:james@wagnerreg.com) or telephone at (302) 535-7290 if you have any questions.

Respectfully submitted,

A handwritten signature in cursive script, reading "James M. Wagner", is written above the typed name.

James M. Wagner  
Agent for Rotam Limited

Enclosures

## DATA TRANSMITTAL DOCUMENT

1. **Name and Address of Submitter**

Rotam Limited  
c/o Wagner Regulatory Associates  
PO Box 640  
Hockessin, DE 19707

2. **Regulatory Action In Support Of Which This Package Is Submitted**

Rotam Dicamba Technical  
EPA Reg. No. 81598-12  
Application for Alternate Source of TGAI

3. **Transmittal Date**

January 19, 2015

4. **List of Submitted Studies**

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Rotam Dicamba Technical: Product Identity and Composition, Description of Materials and Production Process, Discussion of Formation and Toxicity of Impurities, Certified Limits. OPPTS Guideline 830.1550, 830.1600, 830.1620, 830.1670, and 830.1750.

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Preliminary Analysis and Enforcement Analytical Methods for Dicamba TGAI: Selected Studies to Fulfill the Requirements of OPPTS Guideline 830.1700 and 830.1800

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Polychlorinated Dibenzodioxins and Polychlorinated Dibenzofurans Analysis of Dicamba Technical Grade Active Ingredient. OPPTS Guidelines 830.1670, 830.1700 and 830.1800.

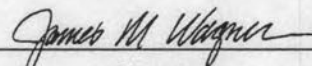
---

Product Chemistry of Dicamba TGAI: Selected Studies to Fulfill the Requirements of OPPTS Guideline Series 830

---

**Company Official:**

James M. Wagner  
Authorized Agent

  
Signature

**Company Name:** Rotam Limited

**Company Contact:** James M. Wagner  
Authorized Agent

(302) 635-7290  
Phone



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**1200 Pennsylvania Avenue, N.W.**  
**WASHINGTON, D.C. 20460**

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**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number Rotam Limited, c/o Wagner Regulatory Associates, P.O. Box 640, Hockessin, DE 19707	EPA Registration Number/File Symbol 81598-12
Active Ingredient(s) and/or representative test compound(s) Dicamba	Date January 15, 2015
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Food and Non Food	Product Name Rotam Dicamba Technical

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT (Check one method only)**

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
--	---

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

**I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.**

Signature 	Date 1/19/2015	Typed or Printed Name and Title James M. Wagner, Agent
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United States  
**Environmental Protection Agency**  
 Washington, DC 20460

Registration	OPP Identifier Number
<input checked="" type="checkbox"/> Amendment	
Other	

### Application for Pesticide - Section I

1. Company/Product Number 81598-12	2. EPA Product Manager Kathryn Montague	3. Proposed Classification  <input checked="" type="checkbox"/> None      Restricted
4. Company/Product (Name) Rotam Limited / Rotam Dicamba Technical	PM# Product Manager Team 23	
5. Name and Address of Applicant (Include Zip Code)  Rotam Limited c/o Wagner Regulatory Associates, Inc. P.O. Box 640 Hockessin, DE 19707  <input type="checkbox"/> Check if this is a new address		6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. Product Name:

### Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)

**PRIA Category R351: Amendment adding a new unregistered source of active ingredient.**

### Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes"      No. per Unit Packaging wgt.      container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes"      No. per Package wgt.      container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) HDPE lined bags
* <b>Certification must be submitted</b>			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container Bulk	5. Location of Label Directions <input type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

### Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)			
Name James Wagner	Title Agent for Rotam Limited	Telephone No. (Include Area Code) (302) 635-7290	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received  (Stamped) 
2. Signature 	3. Title Agent for Rotam Limited		
4. Typed Name James M. Wagner	5. Date January 19, 2015		





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401 M Street, S.W.

WASHINGTON, D.C. 20460

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## DATA MATRIX

Date: January 19, 2015	EPA Reg No./ File Symbol: 81598-12	Page 1 of 4
Applicant's/Registrant's Name and Address: Rotam Limited c/o Wagner Regulatory Associates Inc. P.O. Box 640 Hockessin, DE 19707	Product: Rotam Dicamba Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<b>PRODUCT SPECIFIC</b>					
830.1550, 830.1600,	Product identity, composition/Description of materials Used to Produce the Product		Rotam Limited	Own	
830.1620	Description of Production Process		Rotam Limited	Own	
830.1670	Discussion of Formation of Impurities		Rotam Limited	Own	
830.1700	Preliminary Analysis		Rotam Limited	Own	
830.1750	Certification of Limits		Rotam Limited	Own	
830.1800	Enforcement Analytical Method		Rotam Limited	Own	
830.6302	Color		Rotam Limited	Own	
830.6303	Physical State		Rotam Limited	Own	
830.6304	Odor		Rotam Limited	Own	
830.6313	Stability to Normal & Elevated Temperatures		Rotam Limited	Own	
830.6314	Oxidation/Reduction		Rotam Limited	Own	
830.6315	Flammability	48420504	Rotam Limited	Own	
830.6316	Explosibility	48420504	Rotam Limited	Own	
830.6317	Storage Stability		Rotam Limited	Own	
830.6320	Corrosion Characteristics	48420504	Rotam Limited	Own	
830.7000	pH		Rotam Limited	Own	
830.7050	UV/Visible Light Absorption		Rotam Limited	Own	
830.7200	Melting Point		Rotam Limited	Own	
830.7300	Relative Density		Rotam Limited	Own	
830.7370	Disassociation Constants in Water		Rotam Limited	Own	
830.7550	Octanol/Water Partition Coefficient		Rotam Limited	Own	
830.7840	Solubility in Organic Solvents		Rotam Limited	Own	
830.7860	Water Solubility		Rotam Limited	Own	

Signature

Name and Title

James M. Wagner, Agent for Rotam Limited

Date

1/19/2015



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## DATA MATRIX

Date: January 19, 2015	EPA Reg No./ File Symbol: 81598-12	Page 2 of 4
Applicant's/Registrant's Name and Address: Rotam Limited c/o Wagner Regulatory Associates Inc. P.O. Box 640 Hockessin, DE 19707	Product: Rotam Dicamba Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7950	Vapor Pressure	48420504	Rotam Limited	Own	
870.1100	Acute Oral Toxicity	Cite All	BAYER ENVIRONMENTAL SCIENCE RESEARCH TRIANGLE PARK, NC 27709	Pay	
870.1200	Acute Dermal Toxicity		SYNGENTA CROP PROTECTION LLC GREENSBORO, NC 27419	Pay	
870.1300	Acute Inhalation Toxicity		E. I. DU PONT DE NEMOURS AND COMPANY WILMINGTON, DE 19898	Pay	
870.2400	Primary Eye Irritation		NUFARM AMERICAS, INC. MORRISVILLE, N 27560	Pay	
870.2500	Primary Dermal Irritation		THE SCOTTS COMPANY MARYSVILLE, OH 43041	Pay	
870.2600	Dermal Sensitization		BASF CORPORATION RESEARCH TRIANGLE PARK, NC 27709	Pay	
GENERIC DATA	GENERIC DATA		MONSANTO COMPANY WASHINGTON, DC 20005	Pay	
			LEBANON SEABOARD CORPORATION LEBANON PA 17042	Pay	
			SPRAY DRIFT TASK FORCE WASHINGTON, DC 20006	Pay	
			WINFIELD SOLUTIONS, LLC ST. PAUL, MN 55164	Pay	
			AGRICULTURAL REENTRY TASK FORCE 1350 I STREET, N.W. WASHINGTON, DC 20005	Pay	
			FIFRA ENDANGERED SPECIES TASK FORCE, WASHINGTON, DC	Pay	
			RESIDENTIAL EXPOSURE JOINT VENTURE WASHINGTON, DC 2000	Pay	

Signature

Name and Title

James M. Wagner, Agent for Rotam Limited

Date

1/19/2015



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## DATA MATRIX

Date: January 19, 2015	EPA Reg No./ File Symbol: 81598-12	Page 3 of 4
Applicant's/Registrant's Name and Address: Rotam Limited c/o Wagner Regulatory Associates Inc. P.O. Box 640 Hockessin, DE 19707	Product: Rotam Dicamba Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			AGRICULTURAL HANDLER EXPOSURE TASK FORCE MACON,MO 63552	Pay	
			THE ANDERSONS LAWN FERTILIZER DIV. MAUMEE, OH 43537	Pay	
			PBI GORDON CORP. KANSAS CITY, MO 64101	Pay	
			RITTER CHEMICAL, LLC HOUSTON, TX 77041	Pay	
			CHEMSICO ST. LOUIS, MO 63114	Pay	
			LOVELAND PRODUCTS, INC. GREELEY, CO 80632	Pay	
			NUFARM LIMITED MORRISVILLE, NC 27560	Pay	
			ALBAUGH, INC. VALDOSTA, GA 31064	Pay	
			DOW AGROSCIENCES, LLC INDIANAPOLIS, IN 46268	Pay	
			REPAR CORP. WASHINGTON, DC 20036	Pay	
			PETRO-CANADA LUBRICANTS INC. WASHINGTON, DC 20036	Pay	
			GHARDA USA, INC. NEWTOWN, PA 18940	Pay	
			OUTDOOR RESIDENTIAL EXPOSURE TASK FORCE WASHINGTON, DC 20005	Pay	
			MEY CORPORATION CHAPEL HILL, NC 27514	Pay	
			LIBERTAS NOW, INC. WILMINGTON, DE 19801	Pay	

Signature

Name and Title

James M. Wagner, Agent for Rotam Limited

Date

1/19/2015



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WASHINGTON, D.C. 20460

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## DATA MATRIX

Date: January 19, 2015	EPA Reg No./ File Symbol: 81598-12	Page 4 of 4
Applicant's/Registrant's Name and Address: Rotam Limited c/o Wagner Regulatory Associates Inc. P.O. Box 640 Hockessin, DE 19707	Product: Rotam Dicamba Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			NUFARM INC. MORRISVILLE, NC	Pay	
			BAYER ADVANCED, RESEARCH TRIANGLE PARK, NC	Pay	
			DIRECT AG SOURCE, LLC BROOKFIELD, CT 06804	Pay	
			TACOMA AG, LLC BROOKFIELD, CT 06804	Pay	
			SHARDA USA LLC HOCKESSIN, DE 19707	Pay	
			GHARDA GENERICS, INC. SARASOTA, FL 34238	Pay	
			AGRIUM ADVANCED TECHNOLOGIES HOCKESSIN, DE 19707	Pay	
			BAYER CROPSCIENCE, LP RESEARCH TRIANGLE PARK, NC	Pay	
			BASF CORPORATION, RESEARCH TRIANGLE PARK, NC	Pay	

91.23.10

Signature 	Name and Title James M. Wagner, Agent for Rotam Limited	Date 1/19/2015
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

June 22, 2015

James M. Wagner  
Rotam Limited  
c/o Wagner Regulatory Associates, Inc.  
P.O. Box 640  
Hockessin, DE 10707

Subject: PRIA CSF Amendment – Add a new source of active ingredient to include an Alternate CSF #2  
Product Name: Rotam Dicamba Technical  
EPA Registration Number: 81598-12  
Application Date: 11/15/2014  
Decision Number: 497433

Dear Mr. Wagner:

The Confidential Statement of Formula (CSF) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 09/06/2011
- Alternate CSF 1 dated 12/04/2014
- Alternate CSF 2 dated 11/15/2014

Any CSFs other than those listed above are superseded/no longer valid. If you have any questions, please contact Karen Samek by phone at (703) 347-8825, or via email at [samek.karen@epa.gov](mailto:samek.karen@epa.gov).

Sincerely,

A handwritten signature in cursive script that reads "Kathryn V. Montague".

Kathryn Montague, Product Manager 23  
Herbicide Branch  
Registration Division (7505P)  
Office of Pesticide Programs



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS  
REGISTRATION DIVISION (7505P)

**FEE**

**DP BARCODE: 424886; Reg. No. No.:81598-12 PRODUCT NAME: Rotam Dicamba  
Technical: DECISION NO.: 497433; PC CODE(s): 029801; ACTION CODE: R351**

DATE OUT: 04/22/15

SUBJECT: Product Chemistry Review of Rotam Dicamba Technical

FROM: Indira Gairola / Product Chemistry Team  
CITAB/RD (7505P)

TO: Karen Samek / Kathryn Montague PM 23  
Herbicide Branch / RD (7505P)

(d) 04/22/15

SPB 04/28/15

REGISTRANT: Rotam Limited  
MRID Numbers: 495142-01 to -03

#### INTRODUCTION:

Rotam Limited is proposing amendment to add a new source of active ingredient for Rotam Dicamba Technical to include Alternate CSF #2 dated 11/15/14 that will be produced by [REDACTED] Applicant submitted product Chemistry Guideline reference 830 Subgroup A data with MRID #495142-01 to -03 for alternate CSF#2 dated 11/15/14. CITAB has been asked to determine the acceptability of the product chemistry data and the aforementioned alternate formulation CSF.

#### SUMMARY OF FINDINGS:

##### 1. Group A guidelines: (product identity & composition)

The active ingredient was adequately described (MRID#495142-01) in Alternate CSF dated 11/15/14. The nominal concentration of the active ingredient proposed on the Alternate CSF #2 average 98.76% is within certified limit on the currently approved basic CSF dated 09/06/11.

830.1600 (description of materials used to produce the product)

The registrant has listed the starting materials used at the alternate production site and the relevant data are included in (MRID #495142-01)

830.1620 (description of production process)

The relevant data are included in (MRID #495142-01)

830.1670 (discussion on the formation of impurities)

The nominal concentrations proposed for impurities are the averages derived from the five batch analysis (#495142-03) was provided. According to the Alternate CSF, the product manufactured at the alternate sites does not contain any new impurities of significant toxicological concern. The remaining impurities of significant toxicological concern (Polychlorinated Dibenzodioxins and polychlorinated Dibenzofurans) were analyzed and were determined to be below the level of concern.

830.1700 (preliminary analysis)

The submitted data are acceptable. Results are presented for a five-batch analysis of the active ingredient (MRID #495142-02) was determined by HPLC/ UV Detector using external standard for analyses. The nominal concentrations of the A.I. at the proposed manufacturing source ranged from (98.39%-99.52%) these within the certified limits with a nominal of (98.76%) listed on the currently submitted Alternate CSF dated ~~10/22/14~~ 11/15/2014. The information presented meets the data requirements for 40CFR 158.345

830.1750 (certified limits)

The upper and lower certified limits for the A.I. are within the range of the guideline OCSPP 830.1750 recommendation. The nominal concentration proposed for the A.I. on the Alternate CSF (98.39%-99.52%) is within the certified limits as stated on the label

830.1800 (enforcement analytical method)

The active ingredient was analyzed by HPLC/ UV Detector using external standard for analyses, Acetonitrile was used as a solvent. (MRID#495142-02). The information presented meets the data requirements for 40 CFR 158.355

2. Group B guidelines (physical-chemical properties):

The Data submitted for the Basic CSF will cover the Group B

## **CONCLUSIONS:**

The CITAB has reviewed the product chemistry data submitted to support the proposed alternate CSF dated 11/15/14 for "Rotam Dicamba Technical" and has concluded that:

1. The data submitted for guidelines 830.1700 (preliminary analysis) and 830.1800 (enforcement analytical method) are acceptable.
2. The relevant data provided for the alternate production sites are included in summary of findings are acceptable.
3. 83.1670 (discussion on the formation of impurities) for guidelines 830.1670. There are impurities of significant toxicological concern on the Alternate CSF#2 dated 11/15/14 as per Agency's Toxicology Branch. Analytical data were submitted to indicate that the impurities of significant toxicological concern (Polychlorinated Dibenzodioxins and polychlorinated Dibenzofurans) were below the level of concern. The data submitted are acceptable.
4. The proposed alternate CSF #2 dated 11/15/14 is acceptable. The lower and upper certified limits for the A.I. are within EPA's Standard Certified Limits.

### **Data for Group B**

The Data submitted for the Basic CSF will cover the Group B requirements.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460  
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION  
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

**DP BARCODE No.:** D424886; **FILE SYMBOL No.:** 81598-12 (screen); **PRODUCT NAME:** Rotam Dicamba Technical; **DECISION No.:** 497433; **PC Code(s):** 029801; **ACTION CODE:** R351; **FOOD Use:** Yes

**DATE OUT:** January 26, 2015

**SUBJECT:** Completeness check screening for end use product "Rotam Dicamba Technical"

**FROM:** Shyam Mathur,  
Product Chemistry Team Leader  
CITAB/RD (7505P)

**TO:** Karen Samek / Kathryn Montague, RM 23  
Herbicide Branch / RD (7505P)

**Company Name:** Rotam Limited  
**Formulation Type:** Herbicide  
**Active Ingredient(s):** Dicamba (98.76%)  
**MRID No(s):** 49514201 to 49514203

**Deficiencies:** No  
(if there are deficiencies they are indicated below each heading as Note 1, Note 2 Etc).

**CONCLUSION:**

**Group A:** Data submitted

**Group B:** Not required

**CSF:** Alternate CSF #2 (dated 11-15-2014; [REDACTED] submitted)

**Product label:** Not required

Note to PM: If the deficiencies are found in the screen results, please inform the registrant and bring back to me or to Joe the corrected deficiencies in response to 10 day letter, so that it can be attached to the original bean, if the data package is still in TRB. New Bean is required in case the bean has been closed by TRB. Thank you.

\*Product ingredient source information may be entitled to confidential treatment\*

## Memorandum

Date: 11 / 26 / 14

To: P M 23, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

**We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.**

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission  
☐ partially accepted submission  
☐ rejected submission



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

November 21, 2014

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

WAGNER REGULATORY ASSOCIATES, INC.  
ROTAM LIMITED  
PO.BOX : 640  
HOCKESSIN, DE 19707

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 18-NOV-14. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



**Receipt for Section 3**

S: 960616 Milestone Email:

Regulatory Type: Product Registration - Section 3  Resubmission: ☐ Yes ☒ No  
Application Type: Amendment  Fee For Service: ☐ Yes ☒ No  
Company: 81598 ROTAM LIMITED  Billable: ☒ Yes ☐ No

Risk Manager: Registration Division, Risk Management Team 23

Product #: 81598-12 Product Name: ROTAM DICAMBA TECHNICAL

Override#:

Me Too Section3:  Me Too Product Name:

Application Date: 17-Nov-2014  OPP Rec'd Date: 18-Nov-2014   
Front End Date: 18-Nov-2014  Risk Manager Send Date:   
FFS Due Date:  Negotiated Due Date:   
OPP Target Date:

Fast Track: ☐ New Ingredient: ☐

Receipt Description:  
AMENDMENT WITH STUDES

Form A: ☐ Signature Date:  Form B: ☐ Signature Date:

New Ingredient Request Date:   
New Ingredient Received Date:

**Receipt Content**

Receipt Content	De
Study	
CSF	

November 15, 2014

Document Processing Desk (REGFEE)  
ATTN: Kathryn Montague, PM Team 23  
Registration Division (7504P)  
U.S. Environmental Protection Agency  
Office of Pesticide Programs  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501



49514200

Dear Ms. Montague:

**Re: Rotam Dicamba Technical, EPA Reg. No. 81598-12**  
**PRIA Category R351: Amendment to Add a New Source of Active Ingredient**

Wagner Regulatory Associates, Inc., on behalf of Rotam Limited, respectfully submits the following documents in order to amend the existing registration to add an additional source for technical grade active ingredient:

- Letter from Rotam Limited appointing Wagner Regulatory Associates, Inc. as its agent
- Application for Pesticide Amendment (8570-1)
- Confidential Statement of Formula (8570-4), 2 copies
- Certification with Respect to Citation of Data (8570-34)
- Data Matrix (8570-35)
- Data Transmittal Document
- 3 copies of data as outlined in the Data Transmittal Document
- Receipt for payment of PRIA fee

For the determination of the PRIA registration service fee, this application qualifies as EPA category R351, fee \$12,596. The fee has been paid through [www.pay.gov](http://www.pay.gov) and a copy of the payment receipt is attached.

Please feel free to contact me via email at [james@wagnerreg.com](mailto:james@wagnerreg.com) or telephone at (302) 635-7290 if you have any questions.

Respectfully submitted,

James M. Wagner  
Agent for Rotam Limited

Enclosures





## DATA TRANSMITTAL DOCUMENT

1. **Name and Address of Submitter**  
Rotam Limited  
c/o Wagner Regulatory Associates  
PO Box 640  
Hockessin, DE 19707
2. **Regulatory Action In Support Of Which This Package Is Submitted**  
Rotam Dicamba Technical  
EPA Reg. No. 81598-12  
Application for Alternate Source of TGA1
3. **Transmittal Date**  
  
November 15, 2014
4. **List of Submitted Studies**

Rotam Dicamba Technical: Product Identity and Composition, Description of Materials and Production Process, Discussion of Formation and Toxicity of Impurities, Certified Limits. OPPTS Guideline 830.1550, 830.1600, 830.1620, 830.1670, and 830.1750.

Preliminary Analysis of Dicamba Technical Grade Active Ingredient. OPPTS Guidelines 830.1700 and 830.1800.

Polychlorinated Dibenzodioxins and Polychlorinated Dibenzofurans Analysis of Dicamba Technical Grade Active Ingredient. OPPTS Guidelines 830.1670, 830.1700 and 830.1800.

**Company Official:**

James M. Wagner  
Authorized Agent

*James M. Wagner*  
Signature

**Company Name:**

Rotam Limited**Company Contact:**

James M. Wagner  
Authorized Agent

(302) 635-7290  
Phone



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

November 19, 2014

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OPP Decision Number: D-497433  
EPA File Symbol or Registration Number: 81598-12  
Product Name: ROTAM DICAMBA TECHNICAL  
EPA Receipt Date: 18-Nov-2014  
EPA Company Number: 81598  
Company Name: ROTAM LIMITED

JAMES WAGNER  
WAGNER REGULATORY ASSOCIATES, INC.  
ROTAM LIMITED  
PO Box 640  
HOCKESSIN, DE 19707-

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R351

AMENDMENT; UNREGISTERED SOURCE OF ACTIVE INGREDIENT;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,

*Peressa Edwards*  
Front End Processing Staff

Information Technology & Resources Management Division

# PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 11-18-14

Experts In-Processing Signature: B.B.

Date 11-19-14

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date \_\_\_\_\_

EPA Reg. Number: <u>81598-12</u>		EPA Receipt Date: <u>11-18-14</u>				
Items for Review				Yes	No	N/A*
1	<b>Application Form</b> (EPA Form 8570-1) signed & complete including package type			X		
2	<b>Confidential Statement of Formula</b> all boxes completed, form signed, and dated (EPA Form 8570-4)			X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
	<i>Technical, water and impurities.</i>					
3	<b>Certification with Respect to Citation of Data</b> (EPA Form 8570-34) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	<b>Formulator's Exemption Statement</b> (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
	<b>Data Matrix</b> (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)			X		
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)	X				
	c) Applicant owns all data (Fee category experts use)					
6	<b>5 Copies of Label</b> ( <u>Electronic labels on CD</u> are encouraged and guidance is available)					X
7	<b>Is the data package consistent with PR Notice 86-5</b>			X		
8	<b>Notice of Filing</b> included with petitions					X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
10	<u>Required Data</u> and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

**Comments:**

Documentation: Pass

Inerts:

Technical, water and Impurities only, no inerts to review.

11-35 Pass

MRD 495142

Status: Pass

TO 11/26/14



\* N/A – Not Applicable

#### Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the [inert Web site](#) and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at [inertsbranch@epa.gov](mailto:inertsbranch@epa.gov) and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the [Chief of Microbial Pesticides Branch](#).

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.



During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

### **Unapproved Inerts Identified on CSFs**

#### **All applications except conventional new products and PIPs**

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

#### **Conventional New Product Applications**

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

#### PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

**Fee for Service**

JK  
{960616\*~

This package includes the following

- ☐ New Registration
- ☒ Amendment

- ☒ Studies?      ☐ Fee Waiver?
- ☐ volpay    % Reduction: \_\_\_\_\_

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr.    23

Receipt No.

S-

960616

EPA File Symbol/Reg. No.

81598-12

Pin-Punch Date:

11/18/2014

☐ This item is NOT subject to FFS action.

Action Code:

Requested:

R351

Granted:

R351

Amount Due: \$ 12,596.00

Parent/Child Decisions:

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: ML Lewis

Date: 11/19/14

Remarks:

SEND TO SIM CLINIC -



**Receipt for Section 3**

S: 960616 Milestone Email:

Regulatory Type: Product Registration - Section 3  Resubmission: ☐ Yes ☒ No

Application Type: Amendment  Fee For Service: ☐ Yes ☒ No

Company: 81598 ROTAM LIMITED ☒ Billable: ☒ Yes ☐ No

Risk Manager: Registration Division, Risk Management Team 23

Product #: 81598-12 Product Name: ROTAM DICAMBA TECHNICAL

Override#:

Me Too Section3:  Me Too Product Name:

Application Date: 17-Nov-2014  OPP Rec'd Date: 18-Nov-2014

Front End Date: 18-Nov-2014  Risk Manager Send Date:

FFS Due Date:  Negotiated Due Date:

OPP Target Date:

Fast Track: ☐ New Ingredient: ☐

Receipt Description:  
AMENDMENT WITH STUDIES

Form A: ☐ Signature Date:  Form B: ☐ Signature Date:

New Ingredient Request Date:   
New Ingredient Received Date:

**Receipt Content**

Receipt Content	De
Study	
CSF	



## Receipt

### Your payment is complete

Pay.gov Tracking ID: 25IFG33N

Agency Tracking ID: 74708424009

Form Name: Pesticide Registration Improvement Act - Prepayment

Application Name: PRIA Service Fees

### Payment Information

Payment Type: Debit or credit card

Payment Amount: \$12596.00

Transaction Date: 11/15/2014 09:38:35 AM EST

Payment Date: 11/15/2014

Registration Number:

Company Name: Rotam Limited

Company Number: 81598

Action Code: R351

### Account Information

Card Holder Name: Cheryl R. Wagner

Billing Address: 7217 Lancaster Pike

Billing Address 2: Suite A

City: Hockessin

Country: United States

State/Province: DE

ZIP/Postal Code: 19707

Card Type: American Express

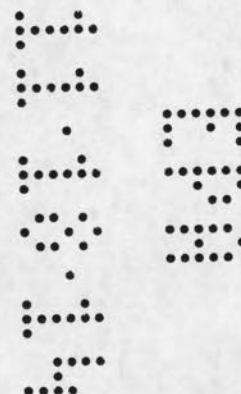
Card Number: \*\*\*\*\*2008

### Email Confirmation Receipt

Confirmation Receipts have been emailed to:

cheryl@wagnerreg.com

carrie@wagnerreg.com





## Cheryl Wagner

---

**From:** pay.gov.clev@clev.frb.org  
**Sent:** Saturday, November 15, 2014 9:39 AM  
**To:** Cheryl Wagner  
**Subject:** Pay.gov Payment Confirmation: PRIA Service Fees

Your payment has been submitted to Pay.gov and the details are below. If you have any questions regarding this payment, please contact Michael Yanchulis at (703) 347-0237 or by email at [yanchulis.michael@epa.gov](mailto:yanchulis.michael@epa.gov).

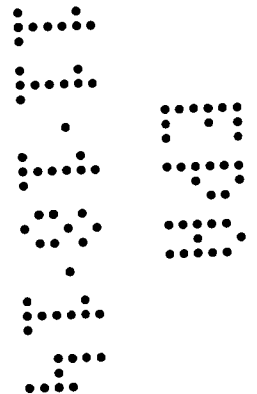
Application Name: PRIA Service Fees  
Pay.gov Tracking ID: 25IFG33N  
Agency Tracking ID: 74708424009  
Transaction Type: Sale  
Transaction Date: 11/15/2014 09:38:35 AM EST

Account Holder Name: Cheryl R. Wagner

Transaction Amount: \$12,596.00  
Billing Address: 7217 Lancaster Pike  
Billing Address 2: Suite A  
City: Hockessin  
State/Province: DE  
Zip/Postal Code: 19707  
Country: USA  
Card Type: AmericanExpress  
Card Number: \*\*\*\*\*2008

Registration Number:  
Company Name: Rotam Limited  
Company Number: 81598  
Action Code: R351

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.





United States  
**Environmental Protection Agency**  
Washington, DC 20460

## Registration

OPP Identifier Number	Agency Name	Activity Title	Start Date	End Date	Status	Comments

X

## Amendment

Other

## Application for Pesticide - Section I

1. Company/Product Number 81598-12	2. EPA Product Manager Kathryn Montague	3. Proposed Classification  <input checked="" type="checkbox"/> None      Restricted
4. Company/Product (Name) Rotam Limited / Rotam Dicamba Technical	PM# Product Manager Team 23	
5. Name and Address of Applicant <i>(Include Zip Code)</i>  Rotam Limited c/o Wagner Regulatory Associates, Inc. P.O. Box 640 Hockessin, DE 19707  <input type="checkbox"/> Check if this is a new address	6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. Product Name:	

## Section - II

<input checked="" type="checkbox"/>	Amendment - Explain below.	<input type="checkbox"/>	Final printed labels in response to Agency letter dated _____
<input type="checkbox"/>	Resubmission in response to Agency letter dated _____	<input type="checkbox"/>	"Me Too" Application.
<input type="checkbox"/>	Notification - Explain below.	<input type="checkbox"/>	Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)

**PRIA Category R351: Amendment adding a new unregistered source of active ingredient.**

## Section - III

**1. Material This Product Will Be Packaged In:**

<b>Child-Resistant Packaging</b> <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	<b>Unit Packaging</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes"                      No. per Unit Packaging wgt.        container 	<b>Water Soluble Packaging</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes"                      No. per Package wgt                container 	<b>2. Type of Container</b> <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) HDPE lined bags
---	--	---	--

\* **Certification must be submitted**

3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container Bulk	5. Location of Label Directions <input type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product
---	-------------------------------------	--

6. Manner in Which Label is Affixed to Product

	Lithograph	<input type="checkbox"/> Other _____
X	Paper glued	
	Stenciled	

.....



## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application):

Name	Title	Telephone No. (Include Area Code)
James Wagner	Agent for Rotam Limited	(302) 635-7290

## Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

2. Signature 	3. Title Agent for Rotam Limited
4. Typed Name James M. Wagner	5. Date 



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**1200 Pennsylvania Avenue, N.W.**  
**WASHINGTON, D.C. 20460**

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number Rotam Limited, c/o Wagner Regulatory Associates, P.O. Box 640, Hockessin, DE 19707	EPA Registration Number/File Symbol 81598-12
Active Ingredient(s) and/or representative test compound(s) Dicamba	Date
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Food and Non Food	Product Name Rotam Dicamba Technical

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT (Check one method only)**

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

*James M. Wagner*

Date

*11/15/04*

Typed or Printed Name and Title

James M. Wagner, Agent



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: November 15, 2014

EPA Reg No./ File Symbol: 81598-12

Page 1 of 4

Applicant's/Registrant's Name and Address: Rotam Limited  
c/o Wagner Regulatory Associates Inc.  
P.O. Box 640  
Hockessin, DE 19707

Product:  
Rotam Dicamba Technical

Ingredient: Dicamba

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<b>PRODUCT SPECIFIC</b>					
830.1550, 830.1600,	Product identity, composition/Description of materials Used to Produce the Product		Rotam Limited	Own	
830.1620	Description of Production Process		Rotam Limited	Own	
830.1670	Discussion of Formation of Impurities		Rotam Limited	Own	
830.1700	Preliminary Analysis		Rotam Limited	Own	
830.1750	Certification of Limits		Rotam Limited	Own	1
830.1800	Enforcement Analytical Method	48420502	Rotam Limited	Own	
830.6302	Color	48420503	Rotam Limited	Own	
830.6303	Physical State	48420503	Rotam Limited	Own	
830.6304	Odor	48420503	Rotam Limited	Own	
830.6313	Stability to Normal & Elevated Temperatures	48420503	Rotam Limited	Own	
830.6314	Oxidation/Reduction	48420503	Rotam Limited	Own	
830.6315	Flammability	48420504	Rotam Limited	Own	
830.6316	Explosibility	48420504	Rotam Limited	Own	
830.6317	Storage Stability	48420504	Rotam Limited	Own	
830.6320	Corrosion Characteristics	48420504	Rotam Limited	Own	
830.7000	pH	48420503	Rotam Limited	Own	
830.7050	UV/Visible Light Absorption	48420503	Rotam Limited	Own	
830.7200	Melting Point	48420503	Rotam Limited	Own	
830.7300	Relative Density	48420503	Rotam Limited	Own	
830.7370	Disassociation Constants in Water	48420504	Rotam Limited	Own	
830.7550	Octanol/Water Partition Coefficient	48420504	Rotam Limited	Own	
830.7840	Solubility in Organic Solvents	48420504	Rotam Limited	Own	
830.7860	Water Solubility	48420504	Rotam Limited	Own	

Signature

Name and Title

James M. Wagner, Agent for Rotam Limited

Date

11/15/2014



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460


Form Approved OMB No. 2070-0060

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: November 15, 2014	EPA Reg No./ File Symbol: 81598-12	Page 2 of 4
Applicant's/Registrant's Name and Address: Rotam Limited c/o Wagner Regulatory Associates Inc. P.O. Box 640 Hockessin, DE 19707	Product: Rotam Dicamba Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7950	Vapor Pressure	48420504	Rotam Limited	Own	
870.1100	Acute Oral Toxicity	Cite All	BAYER ENVIRONMENTAL SCIENCE RESEARCH TRIANGLE PARK, NC 27709	Pay	
870.1200	Acute Dermal Toxicity		SYNGENTA CROP PROTECTION LLC GREENSBORO, NC 27419	Pay	
870.1300	Acute Inhalation Toxicity		E. I. DU PONT DE NEMOURS AND COMPANY WILMINGTON, DE 19898	Pay	
870.2400	Primary Eye Irritation		NUFARM AMERICAS, INC. MORRISVILLE, N 27560	Pay	
870.2500	Primary Dermal Irritation		THE SCOTTS COMPANY MARYSVILLE, OH 43041	Pay	
870.2600	Dermal Sensitization		BASF CORPORATION RESEARCH TRIANGLE PARK, NC 27709	Pay	
GENERIC DATA	GENERIC DATA		MONSANTO COMPANY WASHINGTON, DC 20005	Pay	
			LEBANON SEABOARD CORPORATION LEBANON PA 17042	Pay	
			SPRAY DRIFT TASK FORCE WASHINGTON, DC 20006	Pay	
			WINFIELD SOLUTIONS, LLC ST. PAUL, MN 55164	Pay	
			AGRICULTURAL REENTRY TASK FORCE 1350 I STREET, N.W. WASHINGTON, DC 20005	Pay	
			FIFRA ENDANGERED SPECIES TASK FORCE, WASHINGTON, DC	Pay	
			RESIDENTIAL EXPOSURE JOINT VENTURE WASHINGTON, DC 2000	Pay	

Signature 	Name and Title James M. Wagner, Agent for Rotam Limited	Date 11/15/2014
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## DATA MATRIX

Date: November 15, 2014	EPA Reg No./ File Symbol: 81598-12	Page 3 of 4
Applicant's/Registrant's Name and Address: Rotam Limited c/o Wagner Regulatory Associates Inc. P.O. Box 640 Hockessin, DE 19707	Product: Rotam Dicamba Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			AGRICULTURAL HANDLER EXPOSURE TASK FORCE MACON, MO 63552	Pay	
			THE ANDERSONS LAWN FERTILIZER DIV. MAUMEE, OH 43537	Pay	
			PBI GORDON CORP. KANSAS CITY, MO 64101	Pay	
			RITTER CHEMICAL, LLC HOUSTON, TX 77041	Pay	
			CHEMSICO ST. LOUIS, MO 63114	Pay	
			LOVELAND PRODUCTS, INC. GREELEY, CO 80632	Pay	
			NUFARM LIMITED MORRISVILLE, NC 27560	Pay	
			ALBAUGH, INC. VALDOSTA, GA 31064	Pay	
			DOW AGROSCIENCES, LLC INDIANAPOLIS, IN 46268	Pay	
			REPAR CORP. WASHINGTON, DC 20036	Pay	
			PETRO-CANADA LUBRICANTS INC. WASHINGTON, DC 20036	Pay	
			GHARDA USA, INC. NEWTOWN, PA 18940	Pay	
			OUTDOOR RESIDENTIAL EXPOSURE TASK FORCE WASHINGTON, DC 20005	Pay	
			MEY CORPORATION CHAPEL HILL, NC 27514	Pay	
			LIBERTAS NOW, INC. WILMINGTON, DE 19801	Pay	

Signature 	Name and Title James M. Wagner, Agent for Rotam Limited	Date 11/15/2014
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060


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**DATA MATRIX**

Date: November 15, 2014	EPA Reg No./ File Symbol: 81598-12	Page 4 of 4
Applicant's/Registrant's Name and Address: Rotam Limited c/o Wagner Regulatory Associates Inc. P.O. Box 640 Hockessin, DE 19707	Product: Rotam Dicamba Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			NUFARM INC. MORRISVILLE, NC	Pay	
			BAYER ADVANCED, RESEARCH TRIANGLE PARK, NC	Pay	
			DIRECT AG SOURCE, LLC BROOKFIELD, CT 06804	Pay	
			TACOMA AG, LLC BROOKFIELD, CT 06804	Pay	
			SHARDA USA LLC HOCKESSIN, DE 19707	Pay	
			GHARDA GENERICS, INC. SARASOTA, FL 34238	Pay	
			AGRIUM ADVANCED TECHNOLOGIES HOCKESSIN, DE 19707	Pay	
			BAYER CROPSCIENCE, LP RESEARCH TRIANGLE PARK, NC	Pay	
			BASF CORPORATION, RESEARCH TRIANGLE PARK, NC	Pay	

Footnotes: 1) Certification of Limits is provided in the Confidential Statement of Formula EPA form 8574-4. The 40 CFR 158.350 certification is provided below:

Signature 	Name and Title James M. Wagner, Agent for Rotam Limited	Date 11/15/2014
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March 10, 2014

U.S. Environmental Protection Agency  
Office of Pesticide Programs (7505P)  
One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202

Re: Designation of Agent

Dear Sir or Madam:

This letter serves as notification that **ROTAM LIMITED** (Firm Number: 81598) has appointed Wagner Regulatory Associates, Inc. (WRA, Inc.) to serve as its Agent regarding all pesticide registration matters the company may have with the U.S. Environmental Protection Agency (EPA).

**ROTAM LIMITED** hereby authorizes EPA to contact any of the following individuals within WRA, Inc. on behalf of the company:

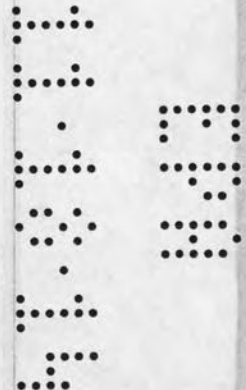
James M. Wagner  
Managing Director  
Wagner Regulatory Associates, Inc.  
P.O. Box 640  
Hockessin, DE 19707  
Telephone: (302) 635-7290  
Fax: (302) 635-7295  
Email: james@wagnerreg.com

Cheryl R. Wagner  
President  
Wagner Regulatory Associates, Inc.  
P.O. Box 640  
Hockessin, DE 19707  
Telephone: (302) 635-7289  
Fax: (302) 635-7295  
Email: Cheryl@wagnerreg.com

Kt Woodall  
Regulatory Associate  
Wagner Regulatory Associates, Inc.  
P.O. Box 640  
Hockessin, DE 19707  
Telephone: (302) 635-7283  
Fax: (302) 635-7295  
Email: Ktwoodall@wagnerreg.com

Carrie Nolan  
Regulatory Associate  
Wagner Regulatory Associates, Inc.  
P.O. Box 640  
Hockessin, DE 19707  
Telephone: (302) 635-7281  
Fax: (302) 635-7295  
Email: Carrie@wagnerreg.com

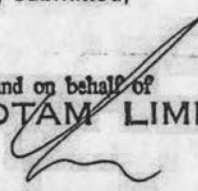
Barbarette Young-Henry  
Regulatory Associate  
Wagner Regulatory Associates, Inc.  
P.O. Box 640  
Hockessin, DE 19707  
Telephone: (302) 635-7279  
Fax: (302) 635-7295  
Email: Barbarette@wagnerreg.com



Authorization to contact these staff members within WRA, Inc remains in effect until such time that ROTAM LIMITED provides notification in writing of any changes.

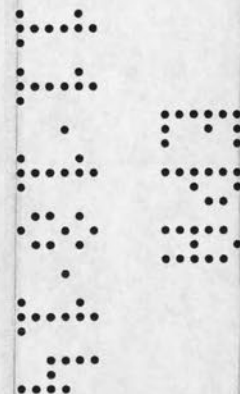
Respectfully submitted,

For and on behalf of  
**ROTAM LIMITED**

  
.....  
*Authorized Signature*

Yifan Wu  
Senior Vice President  
Technical Development Department  
Tel: 86-512-5790 3076  
Fax: 86-512-5771 8692  
Email: yifanwu@rotam.com

cc: WRA, Inc.





# Material Sent for Data Extraction

Reg. # 81598-V2

Description: New Alt#1

☐ Material(s) Sent to Data Extraction Contractors:

☐ New Stamped Label Dated \_\_\_\_\_

☐ Notification Dated \_\_\_\_\_

☒ New CSF(s) Dated Alt#1 12/04/2014

☐ Other: \_\_\_\_\_

☐ Decision #: 491021

☐ Other Action/Comments: \_\_\_\_\_

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Shanta Adeeb

Phone: 347-0502 Division: RD/HB

Date: 347-0502



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

February 3, 2015

James M. Wagner  
Agent Rotam Limited  
c/o Wagner Regulatory Associates, Inc.  
P.O. Box 640  
Hockessin, DE 19707

Subject: PRIA CSF Amendment – Adding Alternate CSF # 1  
Product Name: Rotam Dicamba Technical  
EPA Registration Number: 81598-12  
Application Date: May 7, 2014  
Decision Number: 491021

Dear Mr. Wagner:

The Confidential Statement of Formula (CSF) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

Please note that the record for this product currently contains the following CSFs:

- Basic CSF dated 09/06/2011
- Alternate CSF 1 dated 12/04/2014

Any CSFs other than those listed above are superseded/no longer valid. If you have any questions, please contact Shanta Adeeb by phone at 703-347-0502, or via email at [adeeb.shanta@epa.gov](mailto:adeeb.shanta@epa.gov).

Sincerely,

A handwritten signature in cursive script, reading "Kathryn V. Montague".

Kathryn Montague, Product Manager 23  
Herbicide Branch  
Registration Division (7505P)  
Office of Pesticide Programs



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

**FEE**

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS  
REGISTRATION DIVISION (7505P)

DATE OUT: 20 / January / 2015

SUBJECT: **PRODUCT CHEMISTRY REVIEW OF MP [ X ] EP [ ]**  
DP BARCODE No.: DP424509 EPA Reg. No.: 81598-12  
PRODUCT NAME: Rotam Dicamba Technical  
COMPANY: Rotam Limited.  
FOOD USE [Yes] **INTEGRATED FORMULATION [ X ]**  
PCC: 029801 Decision No. 491021  
ACTION CODE: R351 Pesticide use: Herbicide

FROM: Hari Mukhoty, DVM, Ph.D.  
Product Chemistry Team  
Technical Review Branch / RD (7505P)

*r/mw. S.B. 01-22-15*

TO: Shanta Adeeb, CRM / Kathryn Montague, RM 23  
Herbicide Branch / RD (7505P)

**INTRODUCTION:**

The registrant has submitted an updated alternate CSF (Alt. # 1; Dated 04/12/2014) to the aforesaid basic formulation (EPA Reg. No. 81598-12). Product chemistry data have been submitted in Data Matrix Dated December 4, 2014.

The aforesaid basic and alternate formulation were owned by Ritter Chemicals and on Sept 19, 2013 the Rotam Limited bought these products from Ritter Chemicals. The product chemistry data for the aforesaid basic and alternate formulation were reviewed and found to be acceptable on 09/07/2011.

However, [REDACTED] impurities identified by previous analysis described under MRID: 493775-02 in page 14 were not mentioned in the accepted alternate # 1 CSF (Dated: 09/07/2011). This was pointed out by the product chemistry review dated 11/21/2014 & accepted on 11/25/2014. Because of that reason, the registrant conducted a preliminary analysis of the aforesaid alternate # 1 formulation to detect and quantify those [REDACTED] impurities in the aforesaid formulation and described the results under MRID: 492264-03 as well as in the proposed alt # 1 CSF.

TRB has been requested to evaluate the acceptability of the updated alternate formulation #1.

**SUMMARY OF FINDINGS:**

1. The registrant has reported the quantified amount of the [REDACTED] impurities in the proposed updated alternate formulation # 1 (Dated: 04/12/2014) as required by the product chemistry review dated 11/25/2014.
2. This satisfies the requirements imposed by the product chemistry review of the updated alternate # 1 dated 11/25/2014.

\*Manufacturing process information may be entitled to confidential treatment\*



DP BAR CODE NO.: 424509 EPA Reg. No.: 81598-12 DECISION NO.: 491021

**CONCLUSIONS:**

1. CITAB has reviewed the updated alternate # 1 formulation CSF (Dated: Dec 4, 2014) and found has it to be acceptable.



## Adeeb, Shanta

---

**From:** James Wagner <jmw@wagnerreg.com>  
**Sent:** Tuesday, January 13, 2015 10:24 AM  
**To:** Adeeb, Shanta  
**Subject:** Rotam Dicamba Tech EPA Reg. No. 81598-12 - D491021  
**Attachments:** Request for PRIA Extension.pdf

Dear Shanta,

Enclosed is the letter for PRIA extension.

Best regards,

Jim Wagner  
Regulatory Consultant  
Tel: 302-635-7290  
Mobile: 302-530-5745



Wagner Regulatory Associates, Inc.  
P.O. Box 640  
7217 Lancaster Pike, Suite A  
Hockessin, Delaware 19707

January 13, 2015

Shanta Adeeb  
Registration Division (7504P)  
U.S. Environmental Protection Agency  
Office of Pesticide Programs  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501

Re: Rotam Dicamba Technical, EPA Reg. No. 81598-12  
Request for PRIA Extension for OPP Decision D-491021

Dear Ms. Adeeb:

I am following up on our phone discussion from yesterday regarding this pending action. You explained that there is a possibility that the chemistry review for this action may not be completed in time to meet the current PRIA date of January 29<sup>th</sup>. Therefore, I am requesting a one-month extension of the PRIA in the event that additional time is needed to complete the review.

Sincerely,

James M. Wagner  
Agent for Rotam Limited

Federal Express

December 4, 2014

Document Processing Desk (REGFEE)  
ATTN: Kathryn Montague, PM Team 23  
Registration Division (7504P)  
U.S. Environmental Protection Agency  
Office of Pesticide Programs  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501



Dear Ms. Montague:

**Re: Rotam Dicamba Technical, EPA Reg. No. 81598-12**  
**OPP Decision No. D-491021 – Response to Chemistry Deficiency**

Wagner Regulatory Associates, Inc., on behalf of Rotam Limited, is responding to your data deficiency letter of December 2, 2014 for this product amendment to add a new unregistered source of Dicamba technical produced by [REDACTED]

The Product Chemistry Review dated November 21, 2014 noted a single deficiency in this application: the analyses for certain impurities of toxicological concern were not provided. To resolve this deficiency Rotam has elected to cite existing data on file at the Agency which provides the required information for this Dicamba technical produced by [REDACTED]. The basis for this is provided below.



MRID	Study Citation in NPIRS	Submitter/Submission Date
49226402	Toledo, M. (2013) Qualitative and Quantitative Profile of the Test Substance Dicamba TC (Five Batch Analysis). Project No. 1923/0/022/13. Bioagri Laboratories LTDA. and Jiangsu Changing Agrochemicals Ltd.	Submitter: Nufarm Limited Submission Date: 10/18/13
49270002	Toledo, M. (2013) Qualitative and Quantitative Profile of the Test Substance Dicamba TC (Five Batch Analysis). Project No. 1923/0/022/13. Bioagri Laboratories LTDA and Jiangsu Changing Agrochemicals Ltd..	Submitter: Albaugh, LLC Submission Date: 12/09/13
49377502	Toledo, M. (2013) Qualitative and Quantitative Profile of the Test Substance Dicamba TC (Five Batch Analysis). Project No. 1923/0/022/13. Bioagri Laboratories LTDA and Jiangsu Changing Agrochemicals Ltd..	Submitter: Rotam Ltd. Submission Date: 05/08/14

According to the publically available records on NPIRS, Nufarm also submitted analyses of the impurities of toxicological concern for Dicamba technical produced by [REDACTED] as follows:



MRID	Study Citation	Submitter/Submission Date
49226403	Schoisswohl, D. (2013) Analysis for Tetra- to Octa-Chlorinated Dioxins and Furans in Five Batches of Dicamba TC. Project No. JSC Q/Agro/0613. Jiangsu Changqing Agrochemicals Ltd and UIS Umweltinstitut SynLab GMBH.	Submitter: Nufarm Limited Submission Date: 10/18/13
49258501	Sun, G. (2013) Polychlorinated Dibenzodioxins and Polychlorinated Dibenzofurans Analysis of Dicamba TGAI. Project No. GLP/SP/196, 01/19495/01/001. Southwest Research Institute.	Submitter: Nufarm Limited Submission Date: 11/22/13

On the basis that the above two reports provide analyses of the impurities of toxicological concern for Dicamba technical produced by [REDACTED], which is the same source requested by Rotam Ltd., this resubmission is citing these two reports to resolve the deficiency stated by the Agency for Rotam's application.

In support of this resubmission, I am including the following documents:

- Letter from Rotam Limited appointing Wagner Regulatory Associates, Inc. as its agent
- Agency deficiency letter dated December 2, 2014 with chemistry review dated November 21, 2014
- Confidential Statement of Formula, revised (8570-4), 2 copies
- Certification with Respect to Citation of Data, revised (8570-34)
- Data Matrix, revised(8570-35)

Since the data to resolve this deficiency has already been reviewed by the Agency and the PRIA date is January 29<sup>th</sup>, which is 56 days from today, I respectfully request that the current PRIA date not be extended.

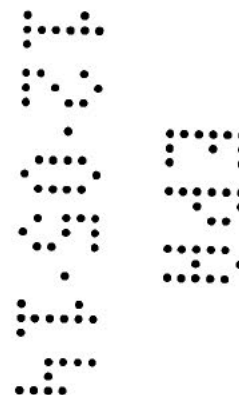
Please contact me via email at james@wagnerreg.com or telephone at (302) 635-7290 if you foresee any problems with this request and resubmission.

Respectfully submitted,



James M. Wagner  
Agent for Rotam Limited

Enclosures







UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
Washington, D.C. 20460

OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

OPP Decision Number: D-491021

James M. Wagner  
Agent  
Rotam Limited  
c/o Wagner Regulatory Associates, Inc.  
P.O. Box 640  
Hockessin, DE 19707

DEC - 2 2014

Subject: Data Deficiency  
Product Name: Rotam Dicamba Technical  
EPA File Symbol: 81598-12  
Application Date: May 7, 2014  
EPA Receipt Date: May 8, 2014

Dear Mr. Wagner:

The Agency has received and begun its in-depth review of the subject application and has determined that it is incomplete or that further information is needed. This letter is a written notification of those deficiencies and identifies your options under 40 CFR 152.105 and Section 33 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended by the Pesticide Registration Improvement Extension Act (PRIA 3). Your options under 40 CFR 152.105 and section 33 of FIFRA are addressed separately because each involves a different timeframe and set of options for responding to this letter. Please ensure that you consider each of the sections below in determining how and when you respond to this letter.

40 CFR 152.105:

The applications referred to above have been determined, pursuant to 40 CFR 152.105, not to be sufficient for further processing. Pursuant to 40 CFR 152.105, you are allowed 75 days from the date of this letter (you must respond by January 15, 2014 due to the PRIA due date of January 29, 2015) to provide a response concerning the deficiencies listed in this letter. Your response may include making corrections or additions to complete the application, or notifying the Agency of the date on which you expect to complete the application, or withdrawing your application. If you do not respond to this letter within 75 days or if you respond with a date on which you expect to complete the application but fail to meet that scheduled date, the Agency will treat the application as if you had withdrawn it. Withdrawal concludes the Agency's review.

of your application. Any subsequent submission of the same application must then be submitted as a new application with a new deadline for EPA to make a determination on your application and subject to a new registration service fee.

The deficiencies identified in the Agency's review at this time are:

1. The product chemistry data submitted did not satisfy the data requirements. Impurities of toxicological concern were not reported.
2. This requirement must be fulfilled before the alternate source can be added to this product.

Further review of your application and your response to the deficiencies may identify additional deficiencies and you will be so informed.

FIFRA Section 33/PRIA:

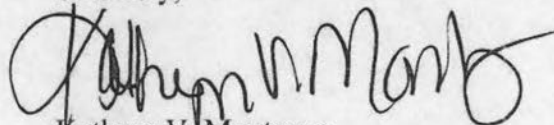
This application is also subject to a deadline for making a determination on the application under FIFRA Section 33, Pesticide Registration Service Fees, established under PRIA. The time frame for the Agency to make a determination on this application ends on January 29, 2015. Because the deadline for the agency to make a determination on this application expires before the end of the 75 days you have to respond to the deficiencies noted above, you have the following three options:

1. **Establish a new due date.** Since the current PRIA date for these actions (January 29, 2015) is less than 75 days from the date of this letter, a renegotiation will be required if you choose to correct these deficiencies. **Please contact the Agency by January 15, 2014** if you intend to correct these deficiencies and require a renegotiated PRIA date. The renegotiated PRIA due date for these actions will be extended by at least 45 days after we receive a resubmission.
2. **Withdraw the application.** Alternatively, you may notify us not later than **January 15, 2014** that you are withdrawing your application. **As noted above, withdrawal concludes the Agency's review of your application;** however, you may resubmit your application after the deficiencies have been addressed. Should you choose to resubmit your application, it would be subject to a new deadline for making a determination on your application and a new registration service fee. Since a fee was paid with this application, the Agency will provide any applicable refund as soon as practicable.
3. **Not respond.** If the Agency does not hear from you by **January 15, 2014**, the Agency in meeting its obligations under section 33/PRIA may issue a determination to not grant your application. While a determination to not grant an application would allow EPA to have met its obligation under section 33 of FIFRA to issue a determination by a specified date, this determination is neither a denial of the application pursuant to section 3(c)(6) of FIFRA or a withdrawal of the application.

Thus, the Agency will continue to diligently work on any such application as long as EPA receives a response to a deficiency notice within the 75 days described above.

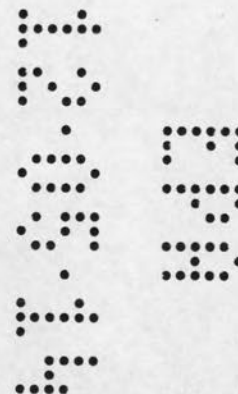
Please respond to this letter by **January 15, 2014** by contacting Shanta Adeeb by telephone on 703-347-0502 or by e-mail at [adeeb.shanta@epa.gov](mailto:adeeb.shanta@epa.gov) or by contacting Kathryn Montague by telephone on 703-305-1243 or by e-mail at [montague.kathryn@epa.gov](mailto:montague.kathryn@epa.gov) during the hours of 8 am to 4 pm EST with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,



Kathryn V. Montague  
Product Manager 23  
Herbicide Branch  
Registration Division (7505P)

Enclosure: Product Chemistry Review of Rotam Dicamba Technical







UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS  
REGISTRATION DIVISION (7505P)

FEE

Date: 11/21/14

SUBJECT: Product Chemistry Review: ROTAM DICAMBA TECHNICAL

FROM: Indira Gairola / Product Chemistry Team  
CITAB/RD (7505P)

TO: Shanta Adeeb / Kathryn Montague PM 23  
Herbicide Branch / Registration Division (7505P)

*Handwritten:* (A) 11/21/14  
*Handwritten:* SBA 11/25/14

DP BARCODE: D420466

DECISION No.: 491021

Registration No.: 81598-12

PRODUCT NAME: Rotam Dicamba Technical

PC Code: 029801

REGISTRANT: ROTAM LIMITED

USE: Herbicide

FOOD USE: Yes ☒ No ☐ MRID Numbers: 493775-01 to -12

#### INTRODUCTION:

The registrant submitted an application for amendment to include a new alternate formulation #1 CSF dated 05/07/14 for source of active ingredient Dicamba Technical that will be produced by [REDACTED]. Applicant is submitting MRID #s 493775-01 to -12.

CITAB (Chemistry Team) has been asked to determine the acceptability of the aforementioned product chemistry data and CSF.

#### SUMMARY OF FINDINGS:

1. Group A guidelines: 830.1550 (Product identity & composition)

Data for the identity and composition of the product were provided. The active ingredient Dicamba is present at a nominal concentration of 97.87%. The product chemistry data submitted corresponding to Guideline 830.1550 satisfy the data requirements of 40CFR§ 158.320.



#### 830.1600 (Description of materials used to produce the product)

The registrant provided a list of suppliers and MSDSs for the materials used to produce the product. The product chemistry data submitted corresponding to Guideline 830.1600 satisfy the data requirements of 40CFR§158.325.

#### 830.1620 (Description of production process)

The production process at by [REDACTED] was described adequately in MRID #493775-01. The product chemistry data submitted corresponding to Guideline 830.1620 satisfy the data requirements of 40CFR§158.330.

#### 830.1670 (Discussion on the formation of impurities)

1. A discussion of the origin and mechanism formation for the impurities in the product was provided in MRID #493775-05. The product chemistry data submitted corresponding to Guideline 830.1760 do not satisfy the data requirements of 40CFR§158.340. Impurities of significant toxicological concern were not reported. Impurities of toxicological concern Polychlorinated dibenzodifurans, dibenzofurans and Dioxane were not analyzed and reported, this is a requirement and must be fulfilled

#### 830.1700 (Preliminary analysis)

Results of a five-batch preliminary analysis were provided. The recovery content of a.i. ranged from 97.25% to 98.24%. These values are within the certified limits specified on the CSF dated 05/07/14. The product chemistry data submitted corresponding to Guideline 830.1700 satisfy the data requirements of 40CFR§158.345.

#### 830.1750 (Certified limits)

Certified limits were provided for the active ingredient, and upper certified limits were provided for the impurities in the product (CSF dated 05/07/14). The product chemistry data submitted corresponding to Guideline 830.1750 satisfy the data requirements of 40CFR§158.350.

#### 830.1800 (Enforcement analytical method)

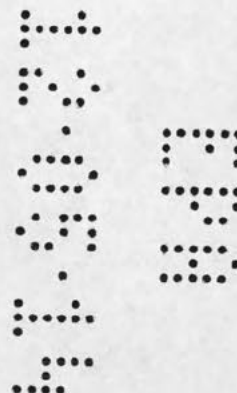
A description of the enforcement analytical method and its validation were provided (MRID #493775-08). The product chemistry data submitted corresponding to Guideline 830.1800 satisfy the data requirements of 40CFR§158.355. Applicant has submitted Enforcement Analytical Method for the subject product however Impurities of toxicological concern Polychlorinated dibenzodifurans and Dioxane were not analyzed and reported, this is a requirement and must be fulfilled

Group B product chemistry data were provided.

## CONCLUSIONS:

The (CITAB/ Product Chemistry Team has reviewed the product chemistry data submitted for the subject product Rotam Dicamba Technical CSF dated 05/07/14 for a registered source of active ingredient produced at alternate site by [REDACTED] and has concluded that:

1. All product chemistry data submitted for guideline 830 Series group A are acceptable except item No.3 as stated below.
2. The proposed alternate source CSF dated 05/07/14 for the subject product can be accepted after the condition (item #3) is satisfied.
3. Applicant has submitted Enforcement Analytical Method for the subject product however Analyses of Impurities of toxicological concern Polychlorinated dibenzodifurans, ~~dibenzo-~~furans and Dioxane must be reported, this is a requirement that must be fulfilled. Please refer to the summary of findings for details.
4. Product chemistry data corresponding to 830 series group B (physical-chemical properties) were submitted. The physical-chemical properties data originally submitted for the basic formulation will fulfill this requirement.



March 10, 2014

U.S. Environmental Protection Agency  
Office of Pesticide Programs (7505P)  
One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202

Re: Designation of Agent

Dear Sir or Madam:

This letter serves as notification that **ROTAM LIMITED** (Firm Number: 81598) has appointed Wagner Regulatory Associates, Inc. (WRA, Inc.) to serve as its Agent regarding all pesticide registration matters the company may have with the U.S. Environmental Protection Agency (EPA).

**ROTAM LIMITED** hereby authorizes EPA to contact any of the following individuals within WRA, Inc. on behalf of the company:

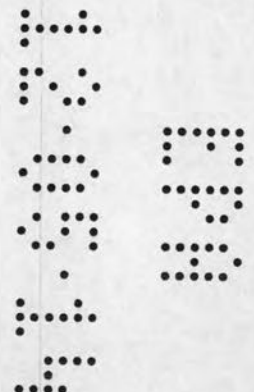
James M. Wagner  
Managing Director  
Wagner Regulatory Associates, Inc.  
P.O. Box 640  
Hockessin, DE 19707  
Telephone: (302) 635-7290  
Fax: (302) 635-7295  
Email: james@wagnerreg.com

Cheryl R. Wagner  
President  
Wagner Regulatory Associates, Inc.  
P.O. Box 640  
Hockessin, DE 19707  
Telephone: (302) 635-7289  
Fax: (302) 635-7295  
Email: Cheryl@wagnerreg.com

Kt Woodall  
Regulatory Associate  
Wagner Regulatory Associates, Inc.  
P.O. Box 640  
Hockessin, DE 19707  
Telephone: (302) 635-7283  
Fax: (302) 635-7295  
Email: Ktwoodall@wagnerreg.com

Carrie Nolan  
Regulatory Associate  
Wagner Regulatory Associates, Inc.  
P.O. Box 640  
Hockessin, DE 19707  
Telephone: (302) 635-7281  
Fax: (302) 635-7295  
Email: Carrie@wagnerreg.com

Barbarette Young-Henry  
Regulatory Associate  
Wagner Regulatory Associates, Inc.  
P.O. Box 640  
Hockessin, DE 19707  
Telephone: (302) 635-7279  
Fax: (302) 635-7295  
Email: Barbarette@wagnerreg.com

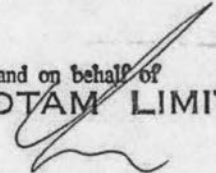




Authorization to contact these staff members within WRA, Inc remains in effect until such time that **ROTAM LIMITED** provides notification in writing of any changes.

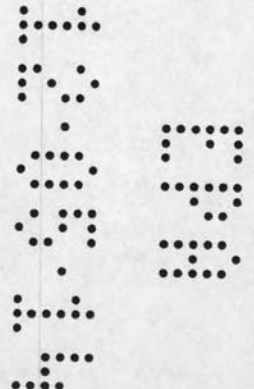
Respectfully submitted,

For and on behalf of  
**ROTAM LIMITED**

  
.....  
*Authorized Signature*

Yifan Wu  
Senior Vice President  
Technical Development Department  
Tel: 86-512-5790 3076  
Fax: 86-512-5771 8692  
Email: yifanwu@rotam.com

cc: WRA, Inc.





**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**1200 Pennsylvania Avenue, N.W.**  
**WASHINGTON, D.C. 20460**

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**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number Rotam Limited, c/o Wagner Regulatory Associates, P.O. Box 640, Hockessin, DE 19707	EPA Registration Number/File Symbol 81598-12
Active Ingredient(s) and/or representative test compound(s) Dicamba	Date December 4, 2014
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Food and Non Food	Product Name Rotam Dicamba Technical

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT** (Check one method only)

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

*James M. Wagner*

Date

12/4/2014

Typed or Printed Name and Title

James M. Wagner, Agent





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

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## DATA MATRIX

Date: December 4, 2014

EPA Reg No./ File Symbol: 81598-12

Page 1 of 5

Applicant's/Registrant's Name and Address: Rotam Limited  
c/o Wagner Regulatory Associates Inc.  
P.O. Box 640  
Hockessin, DE 19707

Product:  
  
Rotam Dicamba Technical

Ingredient: Dicamba

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<b>PRODUCT SPECIFIC</b>					
830.1550, 830.1600,	Product identity, composition/Description of materials Used to Produce the Product	49377501	Rotam Limited	Own	
830.1620	Description of Production Process	49377501	Rotam Limited	Own	
830.1670	Discussion of Formation of Impurities	49377501, 49377505, 49377506,	Rotam Limited	Own	
830.1700	Preliminary Analysis	49377502	Rotam Limited	Own	
830.1700	Preliminary Analysis Impurities of Tox Concern	49226403, 49258501	Nufarm Limited	Pay	
830.1750	Certification of Limits	39377503	Rotam Limited	Own	
830.1800	Enforcement Analytical Method	49377508 49377507	Rotam Limited	Own	
830.1800	Enforcement Analytical Method Impurities of Tox Concern	49226403, 49258501	Nufarm Limited	Pay	
830.6302	Color	49377504	Rotam Limited	Own	
830.6303	Physical State	49377504	Rotam Limited	Own	
830.6304	Odor	49377504	Rotam Limited	Own	
830.6313	Stability to Normal & Elevated Temperatures	49377504	Rotam Limited	Own	
830.6314	Oxidation/Reduction	49377504	Rotam Limited	Own	
830.6315	Flammability	49377504	Rotam Limited	Own	
830.6316	Explosibility	49377504	Rotam Limited	Own	
830.6317	Storage Stability	49377504	Rotam Limited	Own	
830.6320	Corrosion Characteristics	49377504	Rotam Limited	Own	
830.7000	pH	49377504	Rotam Limited	Own	

Signature

Name and Title

James M. Wagner, Agent for Rotam Limited

Date

12/4/2014

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Applicant's/Registrant's Name and Address: Rotam Limited c/o Wagner Regulatory Associates Inc. P.O. Box 640 Hockessin, DE 19707		Product:  Rotam Dicamba Technical	
Ingredient: Dicamba			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7050	UV/Visible Light Absorption	49377504	Rotam Limited	Own	
830.7200	Melting Point	49377509	Rotam Limited	Own	
830.7300	Relative Density	49377504	Rotam Limited	Own	
830.7370	Disassociation Constants in Water	49377504	Rotam Limited	Own	
830.7550	Octanol/Water Partition Coefficient	49377510	Rotam Limited	Own	
830.7840	Solubility in Organic Solvents	49377511	Rotam Limited	Own	
830.7860	Water Solubility	49377511	Rotam Limited	Own	
830.7950	Vapor Pressure	49377512	Rotam Limited	Own	
870.1100	Acute Oral Toxicity	Cite All	BAYER ENVIRONMENTAL SCIENCE P.O. BOX 12014 2 T.W. ALEXANDER DRIVE RESEARCH TRIANGLE PARK, NC 27709	Pay	
870.1200	Acute Dermal Toxicity		SYNGENTA CROP PROTECTION LLC P.O. BOX 18300 410 SWING ROAD GREENSBORO, NC 27419	Pay	
870.1300	Acute Inhalation Toxicity		E. I. DU PONT DE NEMOURS AND COMPANY 1007 MARKET STREET WILMINGTON, DE 19898	Pay	
870.2400	Primary Eye Irritation		NUFARM AMERICAS, INC. 4020 AERIAL CENTER PKWY, SUITE 101 MORRISVILLE, N 27560	Pay	
870.2500	Primary Dermal Irritation		THE SCOTTS COMPANY 14111 SCOTSLAWN ROAD MARYSVILLE, OH 43041	Pay	
870.2600	Dermal Sensitization		BASF CORPORATION P.O. BOX 13528 26 DAVIS DRIVE RESEARCH TRIANGLE PARK, NC 27709	Pay	
GENERIC DATA	GENERIC DATA				

Signature 	Name and Title James M. Wagner, Agent for Rotam Limited	Date 12/4/2014
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Applicant's/Registrant's Name and Address: Rotam Limited c/o Wagner Regulatory Associates Inc. P.O. Box 640 Hockessin, DE 19707		Product:  Rotam Dicamba Technical	
Ingredient: Dicamba			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			MONSANTO COMPANY 1300 I STREET N.W. SUITE 450 EAST WASHINGTON, DC 20005	Pay	
			LEBANON SEABOARD CORPORATION 1600 EAST CUMBERLAND STREET LEBANON PA 17042	Pay	
			SPRAY DRIFT TASK FORCE 1900 K STREET, NW WASHINGTON,DC 20006	Pay	
			WINFIELD SOLUTIONS, LLC P.O. BOX 64589 ST. PAUL, MN 55164	Pay	
			AGRICULTURAL REENTRY TASK FORCE 1350 I STREET, N.W. WASHINGTON,DC 20005	Pay	
			FIFRA ENDANGERED SPECIES TASK FORCE, L 1350 I STREET, NW WASHINGTON,DC 20005	Pay	
			RESIDENTIAL EXPOSURE JOINT VENTURE (RE 1667 K STREET, NW, SUITE 300 WASHINGTON,DC 2000	Pay	
			AGRICULTURAL HANDLER EXPOSURE TASK FOR P.O. Box 509 1720 PROSPECT DRIVE MACON,MO 63552	Pay	
			THE ANDERSONS LAWN FERTILIZER DIV. P.O. BOX 119, 521 ILLINOIS AVENUE MAUMEE, OH 43537	Pay	
			PBI GORDON CORP. P.O. BOX 014090, 1217 WEST 12 <sup>TH</sup> STREET KANSAS CITY, MO 64101	Pay	
			RITTER CHEMICAL, LLC 9300 BAYTHORNE DR. HOUSTON, TX 77041	Pay	

Signature

Name and Title

James M. Wagner, Agent for Rotam Limited

Date

12/4/2014



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Applicant's/Registrant's Name and Address: Rotam Limited c/o Wagner Regulatory Associates Inc. P.O. Box 640 Hockessin, DE 19707		Product: Rotam Dicamba Technical	
Ingredient: Dicamba			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			CHEMSICO P.O.BOX 142642 ST. LOUIS, MO 63114	Pay	
			LOVELAND PRODUCTS, INC. P.O. BOX 1286 GREELEY, CO 80632	Pay	
			NUFARM LIMITED 4020 AERIAL CENTER PKWY., SUITE 103 MORRISVILLE, NC 27560	Pay	
			ALBAUGH, INC. P.O. BOX 2127 VALDOSTA, GA 31064	Pay	
			DOW AGROSCIENCES, LLC 9330 ZIONSVILLE, ROAD 308/2E INDIANAPOLIS, IN 46268	Pay	
			REPAR CORP. 1050 CONNECTICUT AVE., NW, SUITE 1000 WASHINGTON, DC 20036	Pay	
			PETRO-CANADA LUBRICANTS INC. 1330 CONNECTICUT AVENUE N.W. WASHINGTON, DC 20036	Pay	
			GHARDA USA, INC. 660 NEWTOWN-YARDLEY ROAD SUITE 105 NEWTOWN, PA 18940	Pay	
			OUTDOOR RESIDENTIAL EXPOSURE TASK FORCE 1350 I STREET N.W. WASHINGTON, DC 20005	Pay	
			MEY CORPORATION 121 S. ESTES DRIVE, SUITE 101 CHAPEL HILL, NC 27514	Pay	

Signature 	Name and Title James M. Wagner, Agent for Rotam Limited	Date 12/4/2014
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Date: December 4, 2014	EPA Reg No./ File Symbol: 81598-12	Page 5 of 5
Applicant's/Registrant's Name and Address: Rotam Limited c/o Wagner Regulatory Associates Inc. P.O. Box 640 Hockessin, DE 19707	Product: Rotam Dicamba Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			LIBERTAS NOW, INC. 1000 NORTH WEST STREET, SUITE 1200 WILMINGTON, DE 19801	Pay	
			DIRECT AG SOURCE, LLC 115 OBTUSE HILL ROAD BROOKFIELD, CT 06804	Pay	
			TACOMA AG, LLC 115 OBTUSE HILL ROAD BROOKFIELD, CT 06804	Pay	
			SHARDA USA LLC P.O. BOX 640 HOCKESSIN, DE 19707	Pay	
			GHRDA GENERICS, INC. 4032 CROCKERS LAKE BLVD., SUITE 818 SARASOTA, FL 34238	Pay	
			AGRIUM ADVANCED TECHNOLOGIES P.O. BOX 640 HOCKESSIN, DE 19707	Pay	
			AGSAVER II, LLC 1666 K STREET, NW, SUITE 700 WASHINGTON, DC 20006	Pay	
			US RAYMAT AG LLC 4061 NORTH 156 <sup>TH</sup> DRIVE GOODYEAR, AZ 85395	Pay	

Signature 	Name and Title James M. Wagner, Agent for Rotam Limited	Date 12/4/2014
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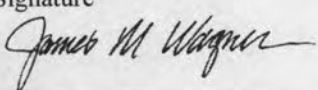
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Applicant's/Registrant's Name and Address: Rotam Limited c/o Wagner Regulatory Associates Inc. P.O. Box 640 Hockessin, DE 19707		Product: Rotam Dicamba Technical	
Ingredient: Dicamba			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
PRODUCT SPECIFIC					
			Rotam Limited	Own	
			Rotam Limited	Own	
			Rotam Limited	Own	
			Rotam Limited	Own	
			Nufarm Limited	Pay	
			Rotam Limited	Own	
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			Nufarm Limited	Pay	
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			Rotam Limited	Own	
			Rotam Limited	Own	

Signature 	Name and Title James M. Wagner, Agent for Rotam Limited	Date 12/4/2014
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401 M Street, S.W.  
WASHINGTON, D.C. 20460

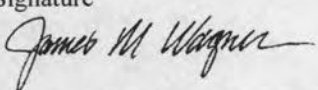
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Applicant's/Registrant's Name and Address: Rotam Limited c/o Wagner Regulatory Associates Inc. P.O. Box 640 Hockessin, DE 19707	Product: Rotam Dicamba Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Rotam Limited	Own	
			Rotam Limited	Own	
			Rotam Limited	Own	
			Rotam Limited	Own	
			Rotam Limited	Own	
			Rotam Limited	Own	
			Rotam Limited	Own	
			Rotam Limited	Own	
			BAYER ENVIRONMENTAL SCIENCE P.O. BOX 12014 2 T.W. ALEXANDER DRIVE RESEARCH TRIANGLE PARK, NC 27709	Pay	
			SYNGENTA CROP PROTECTION LLC P.O. BOX 18300 410 SWING ROAD GREENSBORO, NC 27419	Pay	
			E. I. DU PONT DE NEMOURS AND COMPANY 1007 MARKET STREET WILMINGTON, DE 19898	Pay	
			NUFARM AMERICAS, INC. 4020 AERIAL CENTER PKWY, SUITE 101 MORRISVILLE, N 27560	Pay	
			THE SCOTTS COMPANY 14111 SCOTTS LAWN ROAD MARYSVILLE, OH 43041	Pay	
			BASF CORPORATION P.O. BOX 13528 26 DAVIS DRIVE RESEARCH TRIANGLE PARK, NC 27709	Pay	

Signature 	Name and Title James M. Wagner, Agent for Rotam Limited	Date 12/4/2014
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060



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DATA MATRIX

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Applicant's/Registrant's Name and Address: Rotam Limited c/o Wagner Regulatory Associates Inc. P.O. Box 640 Hockessin, DE 19707	Product:  Rotam Dicamba Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			MONSANTO COMPANY 1300 I STREET N.W. SUITE 450 EAST WASHINGTON, DC 20005	Pay	
			LEBANON SEABOARD CORPORATION 1600 EAST CUMBERLAND STREET LEBANON PA 17042	Pay	
			SPRAY DRIFT TASK FORCE 1900 K STREET, NW WASHINGTON,DC 20006	Pay	
			WINFIELD SOLUTIONS, LLC P.O. BOX 64589 ST. PAUL, MN 55164	Pay	
			AGRICULTURAL REENTRY TASK FORCE 1350 I STREET, N.W. WASHINGTON,DC 20005	Pay	
			FIFRA ENDANGERED SPECIES TASK FORCE, L 1350 I STREET, NW WASHINGTON,DC 20005	Pay	
			RESIDENTIAL EXPOSURE JOINT VENTURE (RE 1667 K STREET, NW, SUITE 300 WASHINGTON,DC 2000	Pay	
			AGRICULTURAL HANDLER EXPOSURE TASK FOR P.O. Box 509 1720 PROSPECT DRIVE MACON,MO 63552	Pay	
			THE ANDERSONS LAWN FERTILIZER DIV. P.O. BOX 119, 521 ILLINOIS AVENUE MAUMEE, OH 43537	Pay	
			PBI GORDON CORP. P.O. BOX 014090, 1217 WEST 12 <sup>TH</sup> STREET KANSAS CITY, MO 64101	Pay	
			RITTER CHEMICAL, LLC 9300 BAYTHORNE DR, HOUSTON, TX 77041	Pay	

Signature

*James M. Wagner*

Name and Title

James M. Wagner, Agent for Rotam Limited

Date

12/4/2014





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060



**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

DATA MATRIX

Date: December 4, 2014	EPA Reg No./ File Symbol: 81598-12	Page 4 of 5
Applicant's/Registrant's Name and Address: Rotam Limited c/o Wagner Regulatory Associates Inc. P.O. Box 640 Hockessin, DE 19707	Product: Rotam Dicamba Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			CHEMSICO P.O.BOX 142642 ST. LOUIS, MO 63114	Pay	
			LOVELAND PRODUCTS, INC. P.O. BOX 1286 GREELEY, CO 80632	Pay	
			NUFARM LIMITED 4020 AERIAL CENTER PKWY., SUITE 103 MORRISVILLE, NC 27560	Pay	
			ALBAUGH, INC. P.O. BOX 2127 VALDOSTA, GA 31064	Pay	
			DOW AGROSCIENCES, LLC 9330 ZIONSVILLE, ROAD 308/2E INDIANAPOLIS, IN 46268	Pay	
			REPAR CORP. 1050 CONNECTICUT AVE., NW. SUITE 1000 WASHINGTON, DC 20036	Pay	
			PETRO-CANADA LUBRICANTS INC. 1330 CONNECTICUT AVENUE N.W. WASHINGTON, DC 20036	Pay	
			GHARDA USA, INC. 660 NEWTOWN-YARDLEY ROAD SUITE 105 NEWTOWN, PA 18940	Pay	
			OUTDOOR RESIDENTIAL EXPOSURE TASK FORCE 1350 I STREET N.W. WASHINGTON, DC 20005	Pay	
			MEY CORPORATION 121 S. ESTES DRIVE, SUITE 101 CHAPEL HILL, NC 27514	Pay	

Signature 	Name and Title James M. Wagner, Agent for Rotam Limited	Date 12/4/2014
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## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060



**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

## DATA MATRIX

Date: December 4, 2014	EPA Reg No./ File Symbol: 81598-12	Page 5 of 5
Applicant's/Registrant's Name and Address: Rotam Limited c/o Wagner Regulatory Associates Inc. P.O. Box 640 Hockessin, DE 19707	Product:  Rotam Dicamba Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			LIBERTAS NOW, INC. 1000 NORTH WEST STREET, SUITE 1200 WILMINGTON, DE 19801	Pay	
			DIRECT AG SOURCE, LLC 115 OBTUSE HILL ROAD BROOKFIELD, CT 06804	Pay	
			TACOMA AG, LLC 115 OBTUSE HILL ROAD BROOKFIELD, CT 06804	Pay	
			SHARDA USA LLC P.O. BOX 640 HOCKESSIN, DE 19707	Pay	
			GHARDA GENERICS, INC. 4032 CROCKERS LAKE BLVD., SUITE 818 SARASOTA, FL 34238	Pay	
			AGRIUM ADVANCED TECHNOLOGIES P.O. BOX 640 HOCKESSIN, DE 19707	Pay	
			AGSAVER II, LLC 1666 K STREET, NW, SUITE 700 WASHINGTON, DC20006	Pay	
			US RAYMAT AG LLC 4061 NORTH 156 <sup>TH</sup> DRIVE GOODYEAR, AZ 85395	Pay	

Signature

Name and Title

James M. Wagner, Agent for Rotam Limited

Date

12/4/2014

86



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
Washington, D.C. 20460

OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

OPP Decision Number: D-491021

James M. Wagner  
Agent  
Rotam Limited  
c/o Wagner Regulatory Associates, Inc.  
P.O. Box 640  
Hockessin, DE 19707

DEC - 2 2014

Subject: Data Deficiency  
Product Name: Rotam Dicamba Technical  
EPA File Symbol: 81598-12  
Application Date: May 7, 2014  
EPA Receipt Date: May 8, 2014

Dear Mr. Wagner:

The Agency has received and begun its in-depth review of the subject application and has determined that it is incomplete or that further information is needed. This letter is a written notification of those deficiencies and identifies your options under 40 CFR 152.105 and Section 33 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended by the Pesticide Registration Improvement Extension Act (PRIA 3). Your options under 40 CFR 152.105 and section 33 of FIFRA are addressed separately because each involves a different timeframe and set of options for responding to this letter. Please ensure that you consider each of the sections below in determining how and when you respond to this letter.

40 CFR 152.105:

The applications referred to above have been determined, pursuant to 40 CFR 152.105, not to be sufficient for further processing. Pursuant to 40 CFR 152.105, you are allowed 75 days from the date of this letter (you must respond by January 15, 2014 due to the PRIA due date of January 29, 2015) to provide a response concerning the deficiencies listed in this letter. Your response may include making corrections or additions to complete the application, or notifying the Agency of the date on which you expect to complete the application, or withdrawing your application. If you do not respond to this letter within 75 days or if you respond with a date on which you expect to complete the application but fail to meet that scheduled date, the Agency will treat the application as if you had withdrawn it. Withdrawal concludes the Agency's review

of your application. Any subsequent submission of the same application must then be submitted as a new application with a new deadline for EPA to make a determination on your application and subject to a new registration service fee.

The deficiencies identified in the Agency's review at this time are:

1. The product chemistry data submitted did not satisfy the data requirements. Impurities of toxicological concern were not reported.
2. This requirement must be fulfilled before the alternate source can be added to this product.

Further review of your application and your response to the deficiencies may identify additional deficiencies and you will be so informed.

#### FIFRA Section 33/PRIA:

This application is also subject to a deadline for making a determination on the application under FIFRA Section 33, Pesticide Registration Service Fees, established under PRIA. The time frame for the Agency to make a determination on this application ends on January 29, 2015. Because the deadline for the agency to make a determination on this application expires before the end of the 75 days you have to respond to the deficiencies noted above, you have the following three options:

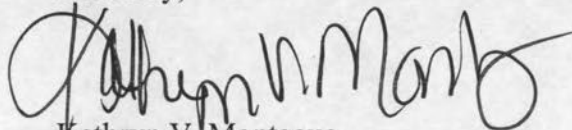
1. **Establish a new due date.** Since the current PRIA date for these actions (January 29, 2015) is less than 75 days from the date of this letter, a renegotiation will be required if you choose to correct these deficiencies. **Please contact the Agency by January 15, 2014** if you intend to correct these deficiencies and require a renegotiated PRIA date. The renegotiated PRIA due date for these actions will be extended by at least 45 days after we receive a resubmission.
2. **Withdraw the application.** Alternatively, you may notify us not later than **January 15, 2014** that you are withdrawing your application. **As noted above, withdrawal concludes the Agency's review of your application;** however, you may resubmit your application after the deficiencies have been addressed. Should you choose to resubmit your application, it would be subject to a new deadline for making a determination on your application and a new registration service fee. Since a fee was paid with this application, the Agency will provide any applicable refund as soon as practicable.
3. **Not respond.** If the Agency does not hear from you by **January 15, 2014**, the Agency in meeting its obligations under section 33/PRIA may issue a determination to not grant your application. While a determination to not grant an application would allow EPA to have met its obligation under section 33 of FIFRA to issue a determination by a specified date, this determination is neither a denial of the application pursuant to section 3(c)(6) of FIFRA or a withdrawal of the application.



Thus, the Agency will continue to diligently work on any such application as long as EPA receives a response to a deficiency notice within the 75 days described above.

Please respond to this letter by **January 15, 2014** by contacting Shanta Adeeb by telephone on 703-347-0502 or by e-mail at [adeeb.shanta@epa.gov](mailto:adeeb.shanta@epa.gov) or by contacting Kathryn Montague by telephone on 703-305-1243 or by e-mail at [montague.kathryn@epa.gov](mailto:montague.kathryn@epa.gov) during the hours of 8 am to 4 pm EST with a response and for any questions concerning this letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kathryn V. Montague', with a large, stylized loop at the end.

Kathryn V. Montague  
Product Manager 23  
Herbicide Branch  
Registration Division (7505P)

Enclosure: Product Chemistry Review of Rotam Dicamba Technical



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS  
REGISTRATION DIVISION (7505P)

FEE

Date: 11/21 /14

SUBJECT: Product Chemistry Review: ROTAM DICAMBA TECHNICAL

FROM: Indira Gairola / Product Chemistry Team  
CITAB/RD (7505P)

TO: Shanta Adeeb / Kathryn Montague PM 23  
Herbicide Branch / Registration Division (7505P)

(A)  
11/21/14

SBR 11/25/14

DP BARCODE: D420466

DECISION No.: 491021

Registration No.: 81598-12

PRODUCT NAME: Rotam Dicamba Technical

PC Code: 029801

REGISTRANT: ROTAM LIMITED

USE: Herbicide

FOOD USE: Yes [X] No [ ] MRID Numbers: 493775-01 to -12

#### INTRODUCTION:

The registrant submitted an application for amendment to include a new alternate formulation #1 CSF dated 05/07/14 for source of active ingredient Dicamba Technical that will be produced by [REDACTED]. Applicant is submitting MRID #s 493775-01 to -12.

CITAB (Chemistry Team) has been asked to determine the acceptability of the aforementioned product chemistry data and CSF.

#### SUMMARY OF FINDINGS:

1. Group A guidelines: 830.1550 (Product identity & composition)

Data for the identity and composition of the product were provided. The active ingredient Dicamba is present at a nominal concentration of 97.87%. The product chemistry data submitted corresponding to Guideline 830.1550 satisfy the data requirements of 40CFR§ 158.320.

#### 830.1600 (Description of materials used to produce the product)

The registrant provided a list of suppliers and MSDSs for the materials used to produce the product. The product chemistry data submitted corresponding to Guideline 830.1600 satisfy the data requirements of 40CFR§158.325.

#### 830.1620 (Description of production process)

The production process at by [REDACTED] was described adequately in MRID #493775-01. The product chemistry data submitted corresponding to Guideline 830.1620 satisfy the data requirements of 40CFR§158.330.

#### 830.1670 (Discussion on the formation of impurities)

1. A discussion of the origin and mechanism formation for the impurities in the product was provided in MRID #493775-05. The product chemistry data submitted corresponding to Guideline 830.1760 do not satisfy the data requirements of 40CFR§158.340. Impurities of significant toxicological concern were not reported. Impurities of toxicological concern Polychlorinated dibenzodifurans, dibenzofurans and Dioxane were not analyzed and reported, this is a requirement and must be fulfilled

#### 830.1700 (Preliminary analysis)

Results of a five-batch preliminary analysis were provided. The recovery content of a.i. ranged from 97.25% to 98.24%. These values are within the certified limits specified on the CSF dated 05/07/14. The product chemistry data submitted corresponding to Guideline 830.1700 satisfy the data requirements of 40CFR§158.345.

#### 830.1750 (Certified limits)

Certified limits were provided for the active ingredient, and upper certified limits were provided for the impurities in the product (CSF dated 05/07/14). The product chemistry data submitted corresponding to Guideline 830.1750 satisfy the data requirements of 40CFR§158.350.

#### 830.1800 (Enforcement analytical method)

A description of the enforcement analytical method and its validation were provided (MRID #493775-08). The product chemistry data submitted corresponding to Guideline 830.1800 satisfy the data requirements of 40CFR§158.355. Applicant has submitted Enforcement Analytical Method for the subject product however Impurities of toxicological concern Polychlorinated dibenzodifurans and Dioxane were not analyzed and reported, this is a requirement and must be fulfilled

Group B product chemistry data were provided.



## CONCLUSIONS:

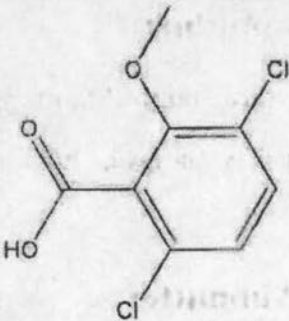
The (CITAB/ Product Chemistry Team has reviewed the product chemistry data submitted for the subject product Rotam Dicamba Technical CSF dated 05/07/14 for a registered source of active ingredient produced at alternate site by [REDACTED] and has concluded that:

1. All product chemistry data submitted for guideline 830 Series group A are acceptable except item No.3 as stated below.
2. The proposed alternate source CSF dated 05/07/14 for the subject product can be accepted after the condition (item #3) is satisfied.
3. Applicant has submitted Enforcement Analytical Method for the subject product however Analyses of Impurities of toxicological concern Polychlorinated dibenzodifurans, ~~dibenzo-~~furans and Dioxane must be reported, this is a requirement that must be fulfilled. Please refer to the summary of findings for details.
4. Product chemistry data corresponding to 830 series group B (physical-chemical properties) were submitted. The physical-chemical properties data originally submitted for the basic formulation will fulfill this requirement.



### 830.1550. Product identity & composition

#### 1. Characteristics of the product:

Common name:	Dicamba
Chemical name:	3,6-Dichloro-2-methoxybenzoic acid
CAS No.:	1918-00-9
Concentration:	960g/kg min.
Molecular formula:	$C_8H_6Cl_2O_3$
Structural formula:	
Molecular weight:	221.0
Appearance:	off-white solid
Day capacity	6T/day
Annual production	2000T/year
1 batch quantity	2T/batch



\*Manufacturing process information may be entitled to confidential treatment\*



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460  
OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION  
OFFICE OF PESTICIDE PROGRAMS REGISTRATION DIVISION (7505P)

DP BARCODE No.: D420466; FILE SYMBOL No.: 81598-12 (screen); PRODUCT NAME: Rotam Dicamba Technical; DECISION No.: 491021; PC Code(s): 029801; ACTION CODE: R351; FOOD Use: Yes

DATE OUT: June 6, 2014

SUBJECT: Completeness check screening for end use product "Rotam Dicamba Technical"

FROM: Shyam Mathur,  
Product Chemistry Team Leader  
Technical Review Branch/RD (7505P)

*SBM 6/6/14*

TO: Shanta Adeeb / Kathryn Montague, RM Team 23  
Herbicide Branch / RD (7505P)

Company Name: Rotam Limited  
Formulation Type: Herbicide  
Active Ingredient(s): Dicamba (97.87%)  
MRID Nos: 493775-01 to 493775-12

CONCLUSION:

Group A: All data submitted

Note 1: The registrant has submitted the toxicity assessment (DEREK) of the [REDACTED] impurities identified in the technical produced at the new site in China

Group B: Selected group B data submitted

CSF: CSF for alternate formulation #1 (dated May 7, 2014; produced at [REDACTED] submitted.

**Product Label: Submitted**

Note to PM: Please bring back to me the corrected deficiencies so that I can attach the revised data in the original bean, if the data package is still in TRB. New Bean is required in case the bean has been closed in TRB. Thank you.

81598-12

R351

## Memorandum

Date: 5 / 19 / 2014

To: 23, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

**We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.**

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission  
☐ partially accepted submission  
☐ rejected submission





**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
WASHINGTON, D.C. 20460

May 19, 2014

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

WAGNER REGULATORY ASSOCIATES, INC.  
ROTAM LIMITED  
PO.BOX : 640  
HOCKESSIN, DE 19707

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 08-MAY-14. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

Receipt for Section 3

S: 952025 Milestone Email:

Regulatory Type: Product Registration - Section 3

Application Type: Amendment

Company: 81598 ROTAM LIMITED

Risk Manager: Registration Division, Risk Management Team 23

Product #: 81598-12 Product Name: ROTAM DICAMBA TECHNICAL

Override#:

Me Too Section3:  Me Too Product Name:

Application Date: 07-May-2014  OPP Rec'd Date: 08-May-2014

Front End Date: 08-May-2014  Risk Manager Send Date:

FFS Due Date:  Negotiated Due Date:

OPP Target Date:

Fast Track: ☐ New Ingredient: ☐

Receipt Description:

Amendment adding a new unregistered source of active ingredient.

Form A: ☐ Signature Date:  Form B: ☐ Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content	Des
Study	
CSF	

View/Edit

49377500



**WRA**

Wagner Regulatory Associates, Inc.  
P.O. Box 640  
7217 Lancaster Pike, Suite A  
Hockessin, Delaware 19707

May 7, 2014

Document Processing Desk (REGFEE)  
ATTN: Kathryn Montague, PM Team 23  
Registration Division (7504P)  
U.S. Environmental Protection Agency  
Office of Pesticide Programs  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501

Dear Ms. Montague:

**Re: Rotam Dicamba Technical, EPA Reg. No. 81598-12**  
**PRIA Category R351: Amendment to Add a New Source of Active Ingredient**

Wagner Regulatory Associates, Inc., on behalf of Rotam Limited, respectfully submits the following documents in order to amend the existing registration to add an additional source for technical grade active ingredient:

- Letter from Rotam Limited appointing Wagner Regulatory Associates, Inc. as its agent
- Application for Pesticide Amendment (8570-1)
- Confidential Statement of Formula (8570-4), 2 copies
- Certification with Respect to Citation of Data (8570-34)
- Data Matrix (8570-35)
- Data Transmittal Document
- 3 copies of data as outlined in the Data Transmittal Document
- Receipt for payment of PRIA fee

For the determination of the PRIA registration service fee, this application qualifies as EPA category R351, fee \$12,596. The fee has been paid through [www.pay.gov](http://www.pay.gov) and a copy of the payment receipt is attached.

Please feel free to contact me via email at [james@wagnerreg.com](mailto:james@wagnerreg.com) or telephone at (302) 635-7290 if you have any questions.

Respectfully submitted,

James M. Wagner  
Agent for Rotam Limited

Enclosures



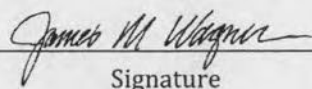
## DATA TRANSMITTAL DOCUMENT

1. **Name and Address of Submitter**  
Rotam Limited  
c/o Wagner Regulatory Associates  
PO Box 640  
Hockessin, DE 19707
2. **Regulatory Action In Support Of Which This Package Is Submitted**  
Rotam Dicamba Technical  
EPA Reg. No. 81598-12  
Application for Alternate Source of TGAI
3. **Transmittal Date**  
May 7<sup>th</sup>, 2014
4. **List of Submitted Studies**

<b>49377501</b>	Rotam Dicamba Technical: Product Identity, Description of Materials and Production Process and Discussion of Formation of Impurities, OPPTS Guideline 830.1550, 1600, 1620, and 1670
<b>49377502</b>	Qualitative and Quantitative Profile of the Test Substance Dicamba TC (Five Batch Analysis) OPPTS Guidelines 830.1700; 830.1800. Study No. 1923.030.022.13
<b>49377503</b>	Rotam Dicamba Technical: Certified Limits, OPPTS Guideline 830.1750
<b>49377504</b>	Dicamba: Physico-Chemical Properties OPPTS Guideline 830 Series. Study No. NAH0001
<b>49377505</b>	Toxicity Assessment of Impurities of Dicamba Technical, OPPTS Guideline 830.1670, Study No. DIBA0003
<b>49377506</b>	<i>In Silico</i> Toxicity Assessment for Impurities of Dicamba using DEREK NEXUS, OPPTS Guideline 830.1670, Study No. DK0146
<b>49377507</b>	Analytical Method Validation for the Active Ingredient Dicamba in Technical Product, OPPTS Guideline 830.1700, 1800, Study No. 1923-032-051.13
<b>49377508</b>	Analytical Method Validation for the Active Ingredient Dicamba in Technical Product, OPPTS Guideline 830.1700, 830.1800, Study No. 1923-032-051.13 Amendment
<b>49377509</b>	Melting Point and Range of Dicamba TC, OPPTS Guideline 830.7200, Study No. 1923.005.023.13
<b>49377510</b>	Partition Coefficient (N-Octanol/Water) of Dicamba TC, OPPTS Guideline 830.7550, Study No. 1923.014.023.13
<b>49377511</b>	Solubility in Water and Organic Solvents of Dicamba TC, OPPTS Guideline 830.7840, Study No. 1923.008.043.13
<b>49377512</b>	Vapor Pressure of Dicamba TC, OPPTS Guideline 830.7950, Study No. 1923.007.024.13

Company Official:

James M. Wagner  
Authorized Agent

  
Signature

Company Name:

Rotam Limited

Company Contact:

James M. Wagner  
Authorized Agent

(302) 635-7290

Phone





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

May 9, 2014

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OPP Decision Number: D-491021  
EPA File Symbol or Registration Number: 81598-12  
Product Name: ROTAM DICAMBA TECHNICAL  
EPA Receipt Date: 08-May-2014  
EPA Company Number: 81598  
Company Name: ROTAM LIMITED

JAMES WAGNER  
WAGNER REGULATORY ASSOCIATES, INC.  
ROTAM LIMITED  
PO Box 640  
HOCKESSIN, DE 19707-

SUBJECT: Receipt of Registration Amendment Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your amendment and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R351

AMENDMENT; UNREGISTERED SOURCE OF ACTIVE INGREDIENT;

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely,  
*Teresa Downs*  
Front End Processing Staff  
Information Technology & Resources Management Division

# Fee for Service

{952025Ã~

This package includes the following

- ☐ New Registration
- ☒ Amendment

☒ Studies?      ☐ Fee Waiver?

☐ volpay    % Reduction: \_\_\_\_

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr.      23

Receipt No.

S- 952025

EPA File Symbol/Reg. No.

81598-12

Pin-Punch Date:

5/8/2014

☐ This item is NOT subject to FFS action.

## Action Code:

Requested: R351

Granted: R351

Amount Due: \$ 12596-

## Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: *E. Fatah*      Date: 5/9/14

Remarks:

# PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 5-8-14

Experts In-Processing Signature: B.B.

Date 5-9-14

Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date \_\_\_\_\_

EPA Reg. Number: <u>81598-12</u>		EPA Receipt Date: <u>5-8-14</u>			
Items for Review			Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type		X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)		X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	<div style="display: flex; justify-content: space-around;"> <span>yes</span> <span>no</span> </div>			
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)		X		
	Certificate and data matrix consistent		X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	<div style="display: flex; justify-content: space-around;"> <span>yes</span> <span>no</span> </div>			
	If applicable, is there a letter of Authorization for exclusive use only.				
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)				X
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)		X		
5	a) Selective Method (Fee category experts use)	<div style="display: flex; justify-content: space-around;"> <span>yes</span> <span>no</span> </div>			
	b) Cite-All (Fee category experts use)				
	c) Applicant owns all data (Fee category experts use)				
6	5 Copies of <u>Label</u> (Electronic labels on <u>CD</u> are encouraged and guidance is available)				X
7	Is the data package consistent with <u>PR Notice 86-5</u>		X		
8	<u>Notice of Filing</u> included with petitions				X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
	<u>Required Data</u> and/or data waivers. See Footnote C.			
10	a) List study (or studies) not included with application			

**Comments:**

Documentation: Pass

- Required forms are complete

Inerts: N/A

- technical & impurities only, no inerts to review

II-B: Pass

- Vol 04, pg 82 missing
- Registrant informed of deficiency on 5/14/2014
- Corrections received 5/15/2014
- MRID 493775

Status: Pass

KC 5/14/2014



\* N/A – Not Applicable

#### Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the inert Web site and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch.

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

### **Unapproved Inerts Identified on CSFs**

#### **All applications except conventional new products and PIPs**

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

#### **Conventional New Product Applications**

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

#### PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

## Script for Rejection Phone calls

Contact Name: James Wagner  
Phone #: (302) 635-7290  
Email: james@wagnerreg.com

First Call/Initials: JC

Date: 5/14/2014

Time: 12:10 pm

Second Call/Initials:

Date:

Time:

This is \_\_\_\_\_, EPA contractor.

I'm calling regarding your submission in support of  
Rotam Dicamba Technical (81598-12).

We have found the following deficiencies regarding PR Notice 86-5 compliance:

Volume/Study Title: Vol. 04 / Physico-Chemical Properties ...  
- pg 82 is missing (corrections received 5/15/2014)

Volume/Study Title:

Volume/Study Title:

Volume/Study Title:

Additional Volumes continued on back of this page: ☐

Application Package: yes or No

These deficiencies have been approved by EPA Contract Officer.

The corrections can be faxed to 703-305-5060/Attn: \_\_\_\_\_.

### Second Call

If we do not receive the corrections by \_\_\_\_\_, we will process your submission accordingly. Please direct all future calls and correspondence to the appropriate EPA Risk Manager.



## Cheryl Wagner

---

**From:** paygovadmin@mail.doc.twai.gov  
**Sent:** Wednesday, May 07, 2014 1:57 PM  
**To:** Cheryl Wagner  
**Subject:** Pay.gov Payment Confirmation: PRIA Service Fees

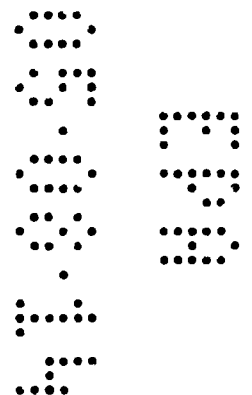
Your payment has been submitted to Pay.gov and the details are below. If you have any questions or you wish to cancel this payment, please contact Pay.gov Customer Service by phone at (800) 624-1373 or by email at [pay.gov.clev@clev.frb.org](mailto:pay.gov.clev@clev.frb.org).

Application Name: PRIA Service Fees  
Pay.gov Tracking ID: 25FKP4QD  
Agency Tracking ID: 74613297998  
Transaction Type: Sale  
Transaction Date: May 7, 2014 1:56:49 PM

Account Holder Name: Cheryl R. Wagner  
Transaction Amount: \$12,596.00  
Billing Address: 7217 Lancaster Pike  
Billing Address 2: Suite A  
City: Hockessin  
State/Province: DE  
Zip/Postal Code: 19707  
Country: USA  
Card Type: AmericanExpress  
Card Number: \*\*\*\*\*1000

Decision Number:  
Registration Number: 81598-12  
Company Name: Rotam Limited  
Company Number: 81598  
Action Code: R351

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.



## Online Payment

## Step 3: Confirm Payment

1 | 2 | 3

Thank you.

Your transaction has been successfully completed.

## Pay.gov Tracking Information

Application Name: PRIA Service Fees

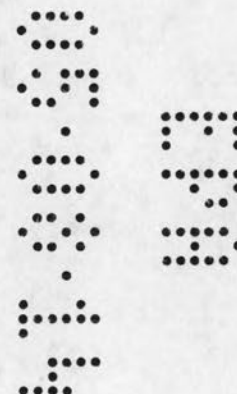
Pay.gov Tracking ID: 25FKP4QD

Agency Tracking ID: 74613297998

Transaction Date and Time: 05/07/2014 13:56 EDT

## Payment Summary

Address Information	Account Information	Payment Information
Account Holder Cheryl R. Name: Wagner 7217 Lancaster Billing Address: Pike Billing Address 2: Suite A City: Hockessin State / Province: DE Zip / Postal Code: 19707 Country: USA	American Card Type: Express Card Number: *****1000 Decision Number: Registration Number: 81598-12 Company Name: Rotam Limited Company Number: 81598 Action Code: R351	Payment Amount: \$12,596.00 Transaction Date 05/07/2014 and Time: 13:56 EDT



May 7, 2014

Document Processing Desk (REGFEE)  
ATTN: Kathryn Montague, PM Team 23  
Registration Division (7504P)  
U.S. Environmental Protection Agency  
Office of Pesticide Programs  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501



Dear Ms. Montague:

**Re: Rotam Dicamba Technical, EPA Reg. No. 81598-12**  
**PRIA Category R351: Amendment to Add a New Source of Active Ingredient**

Wagner Regulatory Associates, Inc., on behalf of Rotam Limited, respectfully submits the following documents in order to amend the existing registration to add an additional source for technical grade active ingredient:

- Letter from Rotam Limited appointing Wagner Regulatory Associates, Inc. as its agent
- Application for Pesticide Amendment (8570-1)
- Confidential Statement of Formula (8570-4), 2 copies
- Certification with Respect to Citation of Data (8570-34)
- Data Matrix (8570-35)
- Data Transmittal Document
- 3 copies of data as outlined in the Data Transmittal Document
- Receipt for payment of PRIA fee

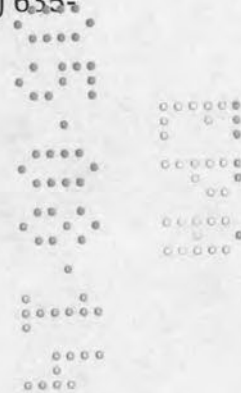
For the determination of the PRIA registration service fee, this application qualifies as EPA category R351, fee \$12,596. The fee has been paid through [www.pay.gov](http://www.pay.gov) and a copy of the payment receipt is attached.

Please feel free to contact me via email at [james@wagnerreg.com](mailto:james@wagnerreg.com) or telephone at (302) 635-7290 if you have any questions.

Respectfully submitted,

James M. Wagner  
Agent for Rotam Limited

Enclosures



COPY 1

**DATA TRANSMITTAL DOCUMENT**

1. **Name and Address of Submitter**

Rotam Limited  
c/o Wagner Regulatory Associates  
PO Box 640  
Hockessin, DE 19707

2. **Regulatory Action In Support Of Which This Package Is Submitted**

Rotam Dicamba Technical  
EPA Reg. No. 81598-12  
Application for Alternate Source of TGAI

3. **Transmittal Date**

May 7<sup>th</sup>, 2014

4. **List of Submitted Studies**

Rotam Dicamba Technical: Product Identity, Description of Materials and Production Process and Discussion of Formation of Impurities, OPPTS Guideline 830.1550, 1600, 1620, and 1670

Qualitative and Quantitative Profile of the Test Substance Dicamba TC (Five Batch Analysis) OPPTS Guidelines 830.1700; 830.1800. Study No. 1923.030.022.13

Rotam Dicamba Technical: Certified Limits, OPPTS Guideline 830.1750

Dicamba: Physico-Chemical Properties OPPTS Guideline 830 Series. Study No. NAH0001

Toxicity Assessment of Impurities of Dicamba Technical, OPPTS Guideline 830.1670, Study No. DIBA0003

*In Silico* Toxicity Assessment for Impurities of Dicamba using DEREK NEXUS, OPPTS Guideline 830.1670, Study No. DK0146

Analytical Method Validation for the Active Ingredient Dicamba in Technical Product, OPPTS Guideline 830.1700, 1800, Study No. 1923-032-051.13

Analytical Method Validation for the Active Ingredient Dicamba in Technical Product, OPPTS Guideline 830.1700, 830.1800, Study No. 1923-032-051.13 Amendment

Melting Point and Range of Dicamba TC, OPPTS Guideline 830.7200, Study No. 1923.005.023.13

Partition Coefficient (N-Octanol/Water) of Dicamba TC, OPPTS Guideline 830.7550, Study No. 1923.014.023.13

Solubility in Water and Organic Solvents of Dicamba TC, OPPTS Guideline 830.7840, Study No. 1923.008.043.13

Vapor Pressure of Dicamba TC, OPPTS Guideline 830.7950, Study No. 1923.007.024.13

Company Official:

James M. Wagner  
Authorized Agent

James M. Wagner  
Signature

Company Name: Rotam Limited

Company Contact: James M. Wagner  
Authorized Agent

(302) 635-7290  
Phone





United States  
**Environmental Protection Agency**  
 Washington, DC 20460

☒
**Registration**

OPP Identifier Number

**Amendment**
**Other**
**Application for Pesticide - Section I**

1. Company/Product Number 81598-12	2. EPA Product Manager Kathryn Montague	3. Proposed Classification  <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Rotam Limited / Rotam Dicamba Technical	PM# Product Manager Team 23	
5. Name and Address of Applicant (Include Zip Code)  Rotam Limited c/o Wagner Regulatory Associates, Inc. P.O. Box 640 Hockessin, DE 19707 <input type="checkbox"/> Check if this is a new address	6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. Product Name:	

**Section - II**

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)

**PRIA Category R351: Amendment adding a new unregistered source of active ingredient.**
**Section - III**

1. <b>Material This Product Will Be Packaged In:</b>			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" No. per Unit Packaging wgt. container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" No. per Package wgt. container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) HDPE lined bags
* <b>Certification must be submitted</b>			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container Bulk	5. Location of Label Directions <input type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

**Section - IV**

1. <b>Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)</b>			
Name James Wagner	Title Agent for Rotam Limited	Telephone No. (Include Area Code) (302) 635-7290	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)	
2. Signature 	3. Title Agent for Rotam Limited		
4. Typed Name James M. Wagner	5. Date May 7, 2014		



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060



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## DATA MATRIX



Date: May 7, 2014

EPA Reg No./ File Symbol: 81598-12

Page 1 of 5

Applicant's/Registrant's Name and Address: Rotam Limited  
c/o Wagner Regulatory Associates Inc.  
P.O. Box 640  
Hockessin, DE 19707

Product:  
Rotam Dicamba Technical

Ingredient: Dicamba

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<b>PRODUCT SPECIFIC</b>					
830.1550, 830.1600,	Product identity, composition/Description of materials Used to Produce the Product	Unassigned	Rotam Limited	Own	1
830.1620	Description of Production Process	Unassigned	Rotam Limited	Own	1
830.1670	Discussion of Formation of Impurities	Unassigned	Rotam Limited	Own	1
830.1700	Preliminary Analysis	Unassigned	Rotam Limited	Own	1
830.1750	Certification of Limits	Unassigned	Rotam Limited	Own	2
830.1800	Enforcement Analytical Method	Unassigned	Rotam Limited	Own	1
830.6302	Color	Unassigned	Rotam Limited	Own	1
830.6303	Physical State	Unassigned	Rotam Limited	Own	1
830.6304	Odor	Unassigned	Rotam Limited	Own	1
830.6313	Stability to Normal & Elevated Temperatures	Unassigned	Rotam Limited	Own	1
830.6314	Oxidation/Reduction	Unassigned	Rotam Limited	Own	1
830.6315	Flammability	Unassigned	Rotam Limited	Own	1
830.6316	Explosibility	Unassigned	Rotam Limited	Own	1
830.6317	Storage Stability	Unassigned	Rotam Limited	Own	1
830.6320	Corrosion Characteristics	Unassigned	Rotam Limited	Own	1
830.7000	pH	Unassigned	Rotam Limited	Own	1
830.7050	UV/Visible Light Absorption	Unassigned	Rotam Limited	Own	1
830.7200	Melting Point	Unassigned	Rotam Limited	Own	1
830.7300	Relative Density	Unassigned	Rotam Limited	Own	1
830.7370	Disassociation Constants in Water	Unassigned	Rotam Limited	Own	1
830.7550	Octanol/Water Partition Coefficient	Unassigned	Rotam Limited	Own	1
830.7840	Solubility in Organic Solvents	Unassigned	Rotam Limited	Own	1
830.7860	Water Solubility	Unassigned	Rotam Limited	Own	1

Signature

Name and Title

James M. Wagner, Agent for Rotam Limited

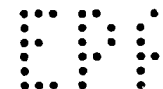
Date

5-7-2014



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060



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**DATA MATRIX**

Date: May 7, 2014	EPA Reg No./ File Symbol: 81598-12	Page 2 of 5
Applicant's/Registrant's Name and Address: Rotam Limited c/o Wagner Regulatory Associates Inc. P.O. Box 640 Hockessin, DE 19707	Product: Rotam Dicamba Technical	
Ingredient: Dicamba		

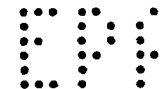
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7950	Vapor Pressure	Unassigned	Rotam Limited	Own	1
870.1100	Acute Oral Toxicity	Cite All	BAYER ENVIRONMENTAL SCIENCE P.O. BOX 12014 2 T.W. ALEXANDER DRIVE RESEARCH TRIANGLE PARK, NC 27709	Pay	
870.1200	Acute Dermal Toxicity		SYNGENTA CROP PROTECTION LLC P.O. BOX 18300 410 SWING ROAD GREENSBORO, NC 27419	Pay	
870.1300	Acute Inhalation Toxicity		E. I. DU PONT DE NEMOURS AND COMPANY 1007 MARKET STREET WILMINGTON, DE 19898	Pay	
870.2400	Primary Eye Irritation		NUFARM AMERICAS, INC. 4020 AERIAL CENTER PKWY, SUITE 101 MORRISVILLE, N 27560	Pay	
870.2500	Primary Dermal Irritation		THE SCOTTS COMPANY 14111 SCOTTS LAWN ROAD MARYSVILLE, OH 43041	Pay	
870.2600	Dermal Sensitization		BASF CORPORATION P.O. BOX 13528 26 DAVIS DRIVE RESEARCH TRIANGLE PARK, NC 27709	Pay	
GENERIC DATA	GENERIC DATA		MONSANTO COMPANY 1300 I STREET N.W. SUITE 450 EAST WASHINGTON, DC 20005	Pay	
			LEBANON SEABOARD CORPORATION 1600 EAST CUMBERLAND STREET LEBANON PA 17042	Pay	
			SPRAY DRIFT TASK FORCE 1900 K STREET, NW WASHINGTON, DC 20006	Pay	

Signature 	Name and Title James M. Wagner, Agent for Rotam Limited	Date 5-7-2014
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060



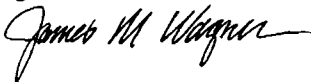
**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. ~~Do not send the form to this address.~~

DATA MATRIX



Date: May 7, 2014		EPA Reg No./ File Symbol: 81598-12	Page 3 of 5
Applicant's/Registrant's Name and Address: Rotam Limited c/o Wagner Regulatory Associates Inc. P.O. Box 640 Hockessin, DE 19707		Product: Rotam Dicamba Technical	
Ingredient: Dicamba			

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			WINFIELD SOLUTIONS, LLC P.O. BOX 64589 ST. PAUL, MN 55164	Pay	
			AGRICULTURAL REENTRY TASK FORCE 1350 I STREET, N.W. WASHINGTON,DC 20005	Pay	
			FIFRA ENDANGERED SPECIES TASK FORCE, L 1350 I STREET, NW WASHINGTON,DC 20005	Pay	
			RESIDENTIAL EXPOSURE JOINT VENTURE (RE 1667 K STREET, NW, SUITE 300 WASHINGTON,DC 2000	Pay	
			AGRICULTURAL HANDLER EXPOSURE TASK FOR P.O. Box 509 1720 PROSPECT DRIVE MACON,MO 63552	Pay	
			THE ANDERSONS LAWN FERTILIZER DIV. P.O. BOX 119, 521 ILLINOIS AVENUE MAUMEE, OH 43537	Pay	
			PBI GORDON CORP. P.O. BOX 014090, 1217 WEST 12 <sup>TH</sup> STREET KANSAS CITY, MO 64101	Pay	
			RITTER CHEMICAL, LLC 9300 BAYTHORNE DR, HOUSTON, TX 77041	Pay	
			CHEMSICO P.O.BOX 142642 ST. LOUIS, MO 63114	Pay	
			LOVELAND PRODUCTS, INC. P.O. BOX 1286 GREELEY, CO 80632	Pay	
			NUFARM LIMITED 4020 AERIAL CENTER PKWY., SUITE 103 MORRISVILLE, NC 27560	Pay	

Signature 	Name and Title James M. Wagner, Agent for Rotam Limited	Date 5-7-2014
---	--	------------------





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060



**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

**DATA MATRIX**

Date: May 7, 2014	EPA Reg No./ File Symbol: 81598-12	Page 4 of 5
Applicant's/Registrant's Name and Address: Rotam Limited c/o Wagner Regulatory Associates Inc. P.O. Box 640 Hockessin, DE 19707	Product: Rotam Dicamba Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			ALBAUGH, INC. P.O. BOX 2127 VALDOSTA, GA 31064	Pay	
			DOW AGROSCIENCES, LLC 9330 ZIONSVILLE, ROAD 308/2E INDIANAPOLIS, IN 46268	Pay	
			REPAR CORP. 1050 CONNECTICUT AVE., NW. SUITE 1000 WASHINGTON, DC 20036	Pay	
			PETRO-CANADA LUBRICANTS INC. 1330 CONNECTICUT AVENUE N.W. WASHINGTON, DC 20036	Pay	
			GHARDA USA, INC. 660 NEWTOWN-YARDLEY ROAD SUITE 105 NEWTOWN, PA 18940	Pay	
			OUTDOOR RESIDENTIAL EXPOSURE TASK FORCE 1350 I STREET N.W. WASHINGTON, DC 20005	Pay	
			MEY CORPORATION 121 S. ESTES DRIVE, SUITE 101 CHAPEL HILL, NC 27514	Pay	
			LIBERTAS NOW, INC. 1000 NORTH WEST STREET, SUITE 1200 WILMINGTON, DE 19801	Pay	
			DIRECT AG SOURCE, LLC 115 OBTUSE HILL ROAD BROOKFIELD, CT 06804	Pay	
			TACOMA AG, LLC 115 OBTUSE HILL ROAD BROOKFIELD, CT 06804	Pay	

Signature 	Name and Title James M. Wagner, Agent for Rotam Limited	Date 5-7-2014
---------------	--	------------------



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.

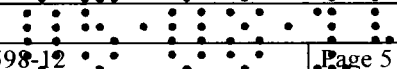
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060



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## DATA MATRIX



Date: May 7, 2014

EPA Reg No./ File Symbol: 81598-12

Page 5 of 5

Applicant's/Registrant's Name and Address: Rotam Limited  
c/o Wagner Regulatory Associates Inc.  
P.O. Box 640  
Hockessin, DE 19707

Product:  
Rotam Dicamba Technical

Ingredient: Dicamba

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			SHARDA USA LLC P.O. BOX 640 HOCKESSIN, DE 19707	Pay	
			GHARDA GENERICS, INC. 4032 CROCKERS LAKE BLVD., SUITE 818 SARASOTA, FL 34238	Pay	
			AGRIUM ADVANCED TECHNOLOGIES P.O. BOX 640 HOCKESSIN, DE 19707	Pay	
			AGSAVER II, LLC 1666 K STREET, NW, SUITE 700 WASHINGTON, DC 20006	Pay	
			US RAYMAT AG LLC 4061 NORTH 156 <sup>TH</sup> DRIVE GOODYEAR, AZ 85395	Pay	

Footnotes: 1) Data is submitted with this application.

2) Certification of Limits is provided in the Confidential Statement of Formula EPA form 8574-4. The 40 CFR 158.350 certification is provided below:

I hereby certify that, for purposes of FIFRA sec. 12(a)(1)(C), the description of the composition of Dicamba Technical, EPA Reg. No. 81598-12 refers to the composition set forth on the Statement of Formula and supporting materials. This description includes the representations that: (1) no ingredient will be present in the product in an amount greater than the upper certified limit or in an amount less than the lower certified limit (if required) specified for that ingredient in a currently approved Statement of Formula (or as calculated by the Agency); and (2) if the Agency requires that the source of supply of an ingredient be specified, that all quantities of such ingredient will be obtained from the source specified in the Statement of Formula.

Signature

Name and Title

James M. Wagner, Agent for Rotam Limited

Date

5-7-2014



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**1200 Pennsylvania Avenue, N.W.**  
**WASHINGTON, D.C. 20460**

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**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number Rotam Limited, c/o Wagner Regulatory Associates, P.O. Box 640, Hockessin, DE 19707	EPA Registration Number/File Symbol 81598-12
Active Ingredient(s) and/or representative test compound(s) Dicamba	Date May 7, 2014
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial Food and Non Food	Product Name Rotam Dicamba Technical

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT** (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
--	---

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature *James M. Wagner*

Date  
May 7, 2014

Typed or Printed Name and Title  
James M. Wagner, Agent







UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060



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DATA MATRIX



Date: May 7, 2014	EPA Reg No./ File Symbol: 81598-12	Page 2 of 5
Applicant's/Registrant's Name and Address: Rotam Limited c/o Wagner Regulatory Associates Inc. P.O. Box 640 Hockessin, DE 19707	Product: Rotam Dicamba Technical	
Ingredient: Dicamba		

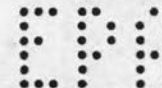
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			BAYER ENVIRONMENTAL SCIENCE P.O. BOX 12014 2 T.W. ALEXANDER DRIVE RESEARCH TRIANGLE PARK, NC 27709	Pay	
			SYNGENTA CROP PROTECTION LLC P.O. BOX 18300 410 SWING ROAD GREENSBORO, NC 27419	Pay	
			E. I. DU PONT DE NEMOURS AND COMPANY 1007 MARKET STREET WILMINGTON, DE 19898	Pay	
			NUFARM AMERICAS, INC. 4020 AERIAL CENTER PKWY, SUITE 101 MORRISVILLE, N 27560	Pay	
			THE SCOTTS COMPANY 14111 SCOTTS LAWN ROAD MARYSVILLE, OH 43041	Pay	
			BASF CORPORATION P.O. BOX 13528 26 DAVIS DRIVE RESEARCH TRIANGLE PARK, NC 27709	Pay	
			MONSANTO COMPANY 1300 I STREET N.W. SUITE 450 EAST WASHINGTON, DC 20005	Pay	
			LEBANON SEABOARD CORPORATION 1600 EAST CUMBERLAND STREET LEBANON PA 17042	Pay	
			SPRAY DRIFT TASK FORCE 1900 K STREET, NW WASHINGTON, DC 20006	Pay	

Signature 	Name and Title James M. Wagner, Agent for Rotam Limited	Date 5-7-2014
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060



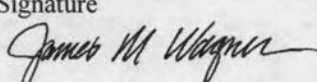
**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instruction and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington DC 20460. Do not send the form to this address.

DATA MATRIX



Date: May 7, 2014	EPA Reg No./ File Symbol: 81598-J2	Page 3 of 5
Applicant's/Registrant's Name and Address: Rotam Limited c/o Wagner Regulatory Associates Inc. P.O. Box 640 Hockessin, DE 19707	Product: Rotam Dicamba Technical	
Ingredient: Dicamba		

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			WINFIELD SOLUTIONS, LLC P.O. BOX 64589 ST. PAUL, MN 55164	Pay	
			AGRICULTURAL REENTRY TASK FORCE 1350 I STREET, N.W. WASHINGTON,DC 20005	Pay	
			FIFRA ENDANGERED SPECIES TASK FORCE, L 1350 I STREET, NW WASHINGTON,DC 20005	Pay	
			RESIDENTIAL EXPOSURE JOINT VENTURE (RE 1667 K STREET, NW, SUITE 300 WASHINGTON,DC 2000	Pay	
			AGRICULTURAL HANDLER EXPOSURE TASK FOR P.O. Box 509 1720 PROSPECT DRIVE MACON,MO 63552	Pay	
			THE ANDERSONS LAWN FERTILIZER DIV. P.O. BOX 119, 521 ILLINOIS AVENUE MAUMEE, OH 43537	Pay	
			PBI GORDON CORP. P.O. BOX 014090, 1217 WEST 12 <sup>TH</sup> STREET KANSAS CITY, MO 64101	Pay	
			RITTER CHEMICAL, LLC 9300 BAYTHORNE DR, HOUSTON, TX 77041	Pay	
			CHEMSICO P.O.BOX 142642 ST. LOUIS, MO 63114	Pay	
			LOVELAND PRODUCTS, INC. P.O. BOX 1286 GREELEY, CO 80632	Pay	
			NUFARM LIMITED 4020 AERIAL CENTER PKWY., SUITE 103 MORRISVILLE, NC 27560	Pay	

Signature 	Name and Title James M. Wagner, Agent for Rotam Limited	Date 5-7-2014
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060



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DATA MATRIX



Date: May 7, 2014

EPA Reg No./ File Symbol: 81598-J2

Page 4 of 5

Applicant's/Registrant's Name and Address: Rotam Limited  
c/o Wagner Regulatory Associates Inc.  
P.O. Box 640  
Hockessin, DE 19707

Product:  
Rotam Dicamba Technical

Ingredient: Dicamba

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			ALBAUGH, INC. P.O. BOX 2127 VALDOSTA, GA 31064	Pay	
			DOW AGROSCIENCES, LLC 9330 ZIONSVILLE, ROAD 308/2E INDIANAPOLIS, IN 46268	Pay	
			REPAR CORP. 1050 CONNECTICUT AVE., NW. SUITE 1000 WASHINGTON, DC 20036	Pay	
			PETRO-CANADA LUBRICANTS INC. 1330 CONNECTICUT AVENUE N.W. WASHINGTON, DC 20036	Pay	
			GHARDA USA, INC. 660 NEWTOWN-YARDLEY ROAD SUITE 105 NEWTOWN, PA 18940	Pay	
			OUTDOOR RESIDENTIAL EXPOSURE TASK FORCE 1350 I STREET N.W. WASHINGTON, DC 20005	Pay	
			MEY CORPORATION 121 S. ESTES DRIVE, SUITE 101 CHAPEL HILL, NC 27514	Pay	
			LIBERTAS NOW, INC. 1000 NORTH WEST STREET, SUITE 1200 WILMINGTON, DE 19801	Pay	
			DIRECT AG SOURCE, LLC 115 OBTUSE HILL ROAD BROOKFIELD, CT 06804	Pay	
			TACOMA AG, LLC 115 OBTUSE HILL ROAD BROOKFIELD, CT 06804	Pay	

Signature

Name and Title

James M. Wagner, Agent for Rotam Limited

Date

5-7-2014





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060



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**DATA MATRIX**



Date: May 7, 2014

EPA Reg No./ File Symbol: 81598-12

Page 5 of 5

Applicant's/Registrant's Name and Address: Rotam Limited  
c/o Wagner Regulatory Associates Inc.  
P.O. Box 640  
Hockessin, DE 19707

Product:  
Rotam Dicamba Technical

Ingredient: Dicamba

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			SHARDA USA LLC P.O. BOX 640 HOCKESSIN, DE 19707	Pay	
			GHARDA GENERICS, INC. 4032 CROCKERS LAKE BLVD., SUITE 818 SARASOTA, FL 34238	Pay	
			AGRIUM ADVANCED TECHNOLOGIES P.O. BOX 640 HOCKESSIN, DE 19707	Pay	
			AGSAVER II, LLC 1666 K STREET, NW, SUITE 700 WASHINGTON, DC20006	Pay	
			US RAYMAT AG LLC 4061 NORTH 156 <sup>TH</sup> DRIVE GOODYEAR, AZ 85395	Pay	

Footnotes: 1) Data is submitted with this application.

2) Certification of Limits is provided in the Confidential Statement of Formula EPA form 8574-4. The 40 CFR 158.350 certification is provided below:

I hereby certify that, for purposes of FIFRA sec. 12(a)(1)(C), the description of the composition of Dicamba Technical, EPA Reg. No. 81598-12 refers to the composition set forth on the Statement of Formula and supporting materials. This description includes the representations that: (1) no ingredient will be present in the product in an amount greater than the upper certified limit or in an amount less than the lower certified limit (if required) specified for that ingredient in a currently approved Statement of Formula (or as calculated by the Agency); and (2) if the Agency requires that the source of supply of an ingredient be specified, that all quantities of such ingredient will be obtained from the source specified in the Statement of Formula.

Signature

Name and Title

James M. Wagner, Agent for Rotam Limited

Date

5-7-2014



# Material Sent for Data Extraction

Reg # 81598-12

Description: PBN

## Material(s) Sent to Data Extraction Contractors:

☐ New Stamped Label Dated \_\_\_\_\_

☒ Notification Dated 11/20<sup>20</sup>/13

☐ New CSF(s) Dated \_\_\_\_\_

☐ Other: \_\_\_\_\_

Decision #: 485106

Other Action/Comments: \_\_\_\_\_

Do not file this cover sheet. Please discard after processing.

Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer: Mindy Ondish

Phone: (703)605-0723 Division: RD/PM Team 25

Date: 11/26/13



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
Washington, D.C. 20460

OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

November 20, 2013

Cheryl Wagner, Agent  
Rotam Limited  
c/o Wagner Regulatory Associates, Inc.  
P.O. Box 640  
Hockessin, DE 19707

Subject: Notification per PR Notice 98-10 (change primary brand name)  
Rotam Dicamba Technical  
EPA Reg. No. 81598-12  
Application Dated November 11, 2013

Dear Ms. Wagner:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the subject product. The Registration Division (RD) has conducted a review of this request and finds that the action falls within the scope of PRN 98-10. The primary brand name for this product has been changed from "Ritter Dicamba Technical" to "Rotam Dicamba Technical". This notification acknowledgement will be uploaded onto PPLS without a label.

If you have any questions, please contact Mindy Ondish at (703)605-0723 or at [ondish.mindy@epa.gov](mailto:ondish.mindy@epa.gov).

Sincerely,

A handwritten signature in black ink, which appears to read "Mindy Ondish, for".

Kathryn V. Montague  
Product Manager 23  
Herbicide Branch  
Registration Division (7505P)  
Office of Pesticide Programs

March 10, 2014

U.S. Environmental Protection Agency  
Office of Pesticide Programs (7505P)  
One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202

Re: Designation of Agent

Dear Sir or Madam:

This letter serves as notification that **ROTAM LIMITED** (Firm Number: 81598) has appointed Wagner Regulatory Associates, Inc. (WRA, Inc.) to serve as its Agent regarding all pesticide registration matters the company may have with the U.S. Environmental Protection Agency (EPA).

**ROTAM LIMITED** hereby authorizes EPA to contact any of the following individuals within WRA, Inc. on behalf of the company:

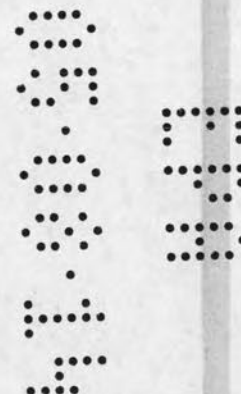
James M. Wagner  
Managing Director  
Wagner Regulatory Associates, Inc.  
P.O. Box 640  
Hockessin, DE 19707  
Telephone: (302) 635-7290  
Fax: (302) 635-7295  
Email: james@wagnerreg.com

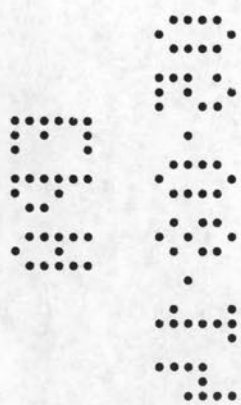
Cheryl R. Wagner  
President  
Wagner Regulatory Associates, Inc.  
P.O. Box 640  
Hockessin, DE 19707  
Telephone: (302) 635-7289  
Fax: (302) 635-7295  
Email: Cheryl@wagnerreg.com

Kt Woodall  
Regulatory Associate  
Wagner Regulatory Associates, Inc.  
P.O. Box 640  
Hockessin, DE 19707  
Telephone: (302) 635-7283  
Fax: (302) 635-7295  
Email: Ktwoodall@wagnerreg.com

Carrie Nolan  
Regulatory Associate  
Wagner Regulatory Associates, Inc.  
P.O. Box 640  
Hockessin, DE 19707  
Telephone: (302) 635-7281  
Fax: (302) 635-7295  
Email: Carrie@wagnerreg.com

Barbarette Young-Henry  
Regulatory Associate  
Wagner Regulatory Associates, Inc.  
P.O. Box 640  
Hockessin, DE 19707  
Telephone: (302) 635-7279  
Fax: (302) 635-7295  
Email: Barbarette@wagnerreg.com







Authorization to contact these staff members within WRA, Inc remains in effect until such time that ROTAM LIMITED provides notification in writing of any changes.

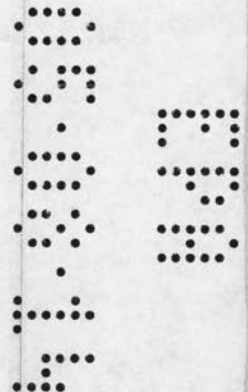
Respectfully submitted,

For and on behalf of  
**ROTAM LIMITED**

.....  
*Authorized Signature*

Yifan Wu  
Senior Vice President  
Technical Development Department  
Tel: 86-512-5790 3076  
Fax: 86-512-5771 8692  
Email: yifanwu@rotam.com

cc: WRA, Inc.





Wagner Regulatory Associates, Inc.  
P.O. Box 640  
7217 Lancaster Pike, Suite A  
Hockessin, Delaware 19707

November 11, 2013

Document Processing Desk (NOTIF)  
ATTN: Kathryn Montague, PM Team 23  
Registration Division  
U.S. Environmental Protection Agency  
Office of Pesticide Programs (7504P)  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, Virginia 22202-4501

Dear Ms. Montague,

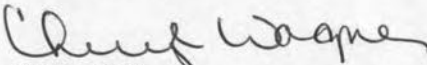
**Subject: Ritter Dicamba Technical, EPA Registration Number 81598-12  
Notification of Change in Primary Brand Name**

Wagner Regulatory Associates, Inc., as agent for Rotam Limited, respectfully notifies the Agency of a change in the primary brand name Ritter Dicamba Technical to **Rotam Dicamba Technical**. In support of this notification, the following documents are enclosed:

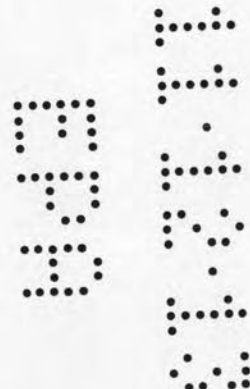
- Letter from Rotam Limited appointing Wagner Regulatory Associates, Inc. as its agent
- Application for Pesticide Notification (8570-1)
- 1 copy of the label

If you have any questions about this submission please contact the undersigned at [Cheryl@wagnerreg.com](mailto:Cheryl@wagnerreg.com) or (302) 635-7289.

Respectfully submitted,

  
Cheryl Wagner  
Agent for Rotam Limited

Enclosures





United States  
**Environmental Protection Agency**  
 Washington, DC 20460

**Registration**  
**Amendment**  
☒ **Other**

OPP Identifier Number

**Application for Pesticide - Section I**

1. Company/Product Number 81598-12	2. EPA Product Manager Kathryn Montague	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Rotam Limited/Ritter Dicamba Technical	PM# 23	
5. Name and Address of Applicant (Include Zip Code) Ritter Chemical, LLC c/o Wagner Regulatory Associates, Inc. P.O. Box 640 Hockessin, DE 19707 <input type="checkbox"/> Check if this is a new address	6. <b>Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. Product Name:  <b>NOTIFICATION</b>  <b>NOV 20 2013</b>	

**Section - II**

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For Section I and Section II.)

Notification of change in primary brand name to Rotam Dicamba Technical. This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

**Section - III**

1. <b>Material This Product Will Be Packaged In:</b>				2. <b>Type of Container</b>	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
	If "Yes" Unit Packaging wgt. No. per container	If "Yes" Package wgt. No. per container		<input checked="" type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) HDPE lined bags	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 2.5 gallons		5. Location of Label Directions <input type="checkbox"/> On Label <input checked="" type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		Other _____			

**Section - IV**

1. <b>Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)</b>					
Name Cheryl Wagner		Title Agent for Rotam Limited		Telephone No. (Include Area Code) (302) 635-7289	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received  (Stamped)
2. Signature 		3. Title Agent for Rotam Limited			
4. Typed Name Cheryl Wagner		5. Date November 11, 2013			

U.S. Environmental Protection Agency  
Office of Pesticide Programs (7505P)  
One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202

February 15, 2012

Re: Designation of Agent

Dear Sir or Madam:

This letter serves as notification that ROTAM LIMITED (Firm Number: 81598) has appointed Wagner Regulatory Associates, Inc. (WRA, Inc.) to serve as its Agent regarding all pesticide registration matters the company may have with the U.S. Environmental Protection Agency (EPA).

ROTAM LIMITED hereby authorizes EPA to contact any of the following individuals within WRA, Inc. on behalf of the company:

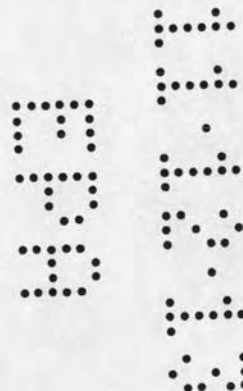
James M. Wagner  
Managing Director  
Wagner Regulatory Associates, Inc.  
P.O. Box 640  
Hockessin, DE 19707  
Telephone: (302) 635-7290  
Fax: (302) 635-7295  
Email: james@wagnerreg.com

Cheryl R. Wagner  
President  
Wagner Regulatory Associates, Inc.  
P.O. Box 640  
Hockessin, DE 19707  
Telephone: (302) 635-7289  
Fax: (302) 635-7295  
Email: Cheryl@wagnerreg.com

Catherine M. Bryd  
Regulatory Associate  
Wagner Regulatory Associates, Inc.  
P.O. Box 640  
Hockessin, DE 19707  
Telephone: (302) 635-7283  
Fax: (302) 635-7295  
Email: Catherine@wagnerreg.com

Lori Kohler  
Regulatory Associate  
Wagner Regulatory Associates, Inc.  
P.O. Box 640  
Hockessin, DE 19707  
Telephone: (302) 635-7281  
Fax: (302) 635-7295  
Email: Lori@wagnerreg.com

Barbarette Young-Henry  
Regulatory Associate  
Wagner Regulatory Associates, Inc.  
P.O. Box 640  
Hockessin, DE 19707  
Telephone: (302) 635-7279  
Fax: (302) 635-7295  
Email: Barbarette@wagnerreg.com





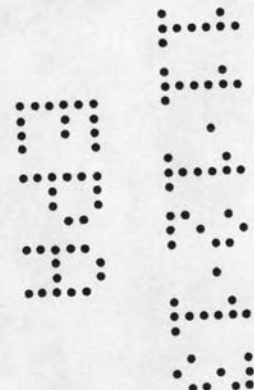
Authorization to contact these staff members within WRA, Inc remains in effect until such time that ROTAM LIMITED provides notification in writing of any changes.

Respectfully submitted,

For and on behalf of  
**ROTAM LIMITED**  
  
.....  
*Authorized Signature*

Yifan Wu  
Vice General Manager  
Tel: 86-512-5790 3076  
Email: yifanwu@rotam.com

cc: WRA, Inc.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

September 18, 2013

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION  
PREVENTION

MS. CHERYL WAGNER  
WAGNER REGULATORY ASSOCIATES, INC., AGENT FOR  
ROTAM LIMITED  
P.O. Box 649  
HOCKESSIN, DE 19707-

Dear Ms. Wagner:

Subject: Transfer of Pesticide Registrations and Data From Company Number 9468 to Company Number 81598

Pursuant to your request in your letter and transfer agreement of August 14, 2013, we have approved the transfer of the following registrations from **RITTER CHEMICAL, LLC**, company number **9468** to **ROTAM LIMITED**, company number **81598**.

The effective date of these changes is the date of this letter.

Registered Products	Old EPA Reg. No.	New EPA Reg. No.
<b>RITTER DICAMBA TECHNICAL</b>	<b>9468-45</b>	<b>81598-12</b>

You should indicate the new company designation, new EPA Registration Number and new Establishment Number (if it has changed) on the labeling at the next printing which should occur no later than 18 months after the effective date of this transfer. After 18 months, any product released for shipment must bear the new Registration Number and Establishment Number. If you intend to use the labels which currently appear on the transferor's product after the effective date of the transfer, but within the 18 month grace period, you must maintain complete and accurate records which identify by batch number, lot number, or other suitable description the quantities of such product bearing the transferor's label. Each container or package bearing the transferor's label which is released after the effective date of product registration transfer, must be clearly and accurately marked with the batch number, lot number or other descriptive designation used to identify the product in your records.

Supplemental distribution agreements of registered products do not transfer with the Section 3 registration. It is your responsibility as the registrant to notify any and all supplemental distributors of the transferred product(s) of this transfer agreement. If you wish to enter into supplemental distribution agreements of your product(s) under this new registration, the form "Notice of Supplemental Distribution of a Registered Pesticide Product," EPA Form 8570-5, must be submitted to the Agency for each supplemental distributorship.

You are required to contact your local EPA Regional Office to determine what effect this transfer of pesticide registrations has on the pesticide production establishment registration.

It will not be necessary to submit labeling for review if the only changes are in the company designation and the EPA Registration Number. Other changes in the product and/or labeling may require EPA review and approval prior to distribution or sale of the product containing the new registration number. In any correspondence on these products always refer to the U.S. EPA Registration Number listed above.

The transferred registration will have the same status under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 USC 136 et seq., as it had prior to the approval of this transfer.

When registrations are transferred from one company to a second company, all restrictions, data requirements, conditions (suspensions), and deadlines existing on the registrations are transferred with the registrations. The new company is responsible for adhering to or complying with all such restrictions, etc. on the acquired products.

With regard to deadlines, the transferee company is responsible for submitting all required data according to the schedules already established for the acquired products. Failure to do so will result in the issuance of a Notice of Intent to Suspend. Requests from transferee companies for additional time to submit, because they acquired the registration(s) after the 3(c)(2)(B) request was issued will not be granted. If a transferee company has other valid reasons for delays in the testing which were clearly outside of their control, then such requests for time extensions will be considered in accordance with the established procedures. Transfers occurring while a 3(c)(2)(B) request is being issued or during the 90-day response time are subject to the same conditions expressed above.

Registration is in no way to be construed as an endorsement or approval of these products by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with FIFRA.

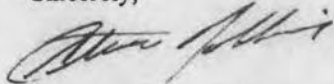
Furthermore, the transfer of the subject registrations is approved under the condition that the annual maintenance fee obligation has been fully satisfied. The annual maintenance fee is based solely on the total number of active section 3 and section 24(c) registrations held by the transferor. If the annual maintenance fee has not been fully satisfied, the transferee and transferor will be notified to comply within a specified time period or the affected registrations may be canceled.

The Agency acknowledges it has received a request for data transfer dated August 14, 2013 to transfer data ownership from the transferor to the transferee. The data transfer is effective the date of this letter. After this date **ROTAM LIMITED** will be considered the data owner. This action will not automatically reflect on the Data Submitters List. If you want to be added to the Data Submitters List, you must submit a request to:

Document Processing Desk (DSL)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Ariel Rios Building  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460

By copy of this letter we are informing the transferor of these changes. If you have any questions about this transfer approval please contact Louis Vaughn at (703) 308-8114.

Sincerely,



Steve Robbins, Chief  
Information Services Branch  
Information Technology & Resource Management Div. (7504P)

cc: MS. JANELLE KAY  
PYXIS REGULATORY CONSULTING, INC., AGENT FOR  
RITTER CHEMICAL, LLC  
4110 136TH STREET, N.W,  
GIG HARBOR, WA 98332-

RE: L\_9468\_RAD\_81598\_09\_18\_2013

## APPENDIX A

MRID or other Identifying Administrative Number	Name of the Study	Name of Person or Lab that Conducted the Study	Date the Study was Submitted to EPA	Is C (
48420501	Tillman, A. (2011) Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Discussion of the Formation of Impurities, Certified Limits, and Enforcement Analytical Method for Ritter Dicamba Technical. Project Number: RC/201006. Unpublished study prepared by Ritter Chemicals, LLC.	Ritter Chemical, LLC	3/16/2011	N
48420502	Li, H. (2011) Preliminary Analysis and Enforcement Analytical Method of Dicamba TGAI - Validation of Analytical Methodology for the Assay of Active Ingredient and Related Significant Impurities and Subsequent 5-Batch Analysis of Dicamba TGAI. Project Number: NC/2007/024. Unpublished study prepared by Nutrichem Laboratory Co., Ltd. 91 p.	Nutrichem Laboratory Co., Ltd.	3/16/2011	N
48420503	Weller, P. (2011) Group B - Product Chemistry Analysis of Dicamba Technical. Project Number: 381100/1/001. Unpublished study prepared by MRIGlobal. 37 p.	MRIGlobal	3/16/2011	N
48420504	Tillman, A. (2011) Ritter Dicamba Technical Waiver Requests for Certain Phys-Chem Properties. Project Number: RC/201007. Unpublished study prepared by Ritter Chemicals, LLC. 15 p.	Ritter Chemical, LLC.	3/16/2011	N



PYXIS REGULATORY CONSULTING, LLC

4110 136<sup>th</sup> St. NW  
Gig Harbor, WA 98332

Phone: 253-853-7369  
Fax: 253-853-5516  
www.PyxisRC.com

December 13, 2011

COURIER DELIVERY

Kathryn Montague (PM 23)  
Document Processing Desk (FNL LBL)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202-4501

RE: Ritter Chemical, LLC  
Ritter Dicamba Technical (EPA Reg. No. 9468-45)  
Submission of Final Product Labeling per the Agency Letter dated October 3, 2011

Dear Ms. Montague,

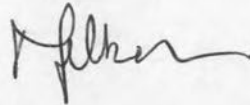
On behalf of Ritter Chemical, LLC, please find the enclosed final product labeling for Ritter Dicamba Technical (EPA Reg. No. 9468-45), per the Agency letter dated October 3, 2011.

In support of this submission, we submit the following:

1. Completed Application for Registration (EPA Form 8570-1)
2. One (1) copy of the Ritter Dicamba Technical final label
3. Letter of Authorization

Please contact me by telephone (253-853-7369) or e-mail (Ross@PyxisRC.com) if you have any questions or need any additional information.

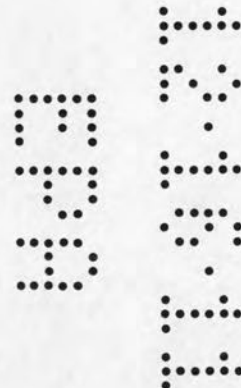
Best regards,



Ross Gilbert

Enclosures

cc: Jaime Smith; Ritter Chemical, LLC





United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☒ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 9468-45	2. EPA Product Manager K. Montague	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Ritter Chemicals, LLC/Ritter Dicamba Technical	PM# 23	
5. Name and Address of Applicant (Include ZIP Code) Ritter Chemicals, LLC c/o Pyxis Regulatory Consulting, Inc. 4110 136th St. NW Gig Harbor, WA 98332 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input checked="" type="checkbox"/> Final printed labels in response to Agency letter dated <u>October 3, 2011</u>
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Submission of final product label per the Agency letter dated October 3, 2011.

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
* Certification must be submitted				<input type="checkbox"/> Plastic	
If "Yes" Unit Packaging wgt. No. per container		If "Yes" Package wgt. No. per container		<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	Polypropylene woven bags
				<input type="checkbox"/> Other (Specify)	
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 800 kg		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Ross Gilbert		Title Agent		Telephone No. (Include Area Code) (253)-853-7369	
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment of both under applicable law.				6. Date Application Received (Stamped) 	
2. Signature 		3. Title Agent			
4. Typed Name Ross Gilbert		5. Date 12/13/2011			



**Ritter Chemical LLC**

October 28, 2009

To Whom It May Concern:

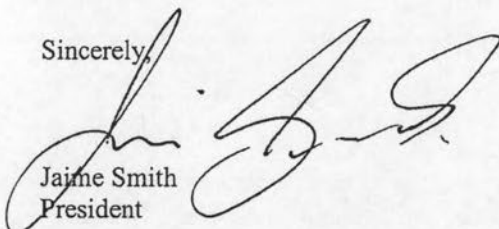
RE: Letter of Authorization

Dear Sir or Madam:

Please let this letter serve to confirm that Pyxis Regulatory Consulting, Inc. is authorized to act as agents for Ritter Chemical, LLC (EPA Company Number 9468), before the U.S. Environmental Protection Agency and state governmental agencies in all matters regarding our pesticide registrations pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq. and state law.

If you have any questions, please do not hesitate to contact me.

Sincerely,



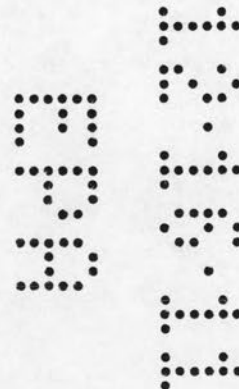
Jaime Smith  
President

cc: Pyxis Regulatory Consulting, Inc.

26099 SW 95th Avenue  
Unit 601  
Wilsonville, OR 97070

Tel 503.218.2980  
Fax 503.293.8372

RitterChemicalLLC.com



**Ritter Dicamba Technical**  
**FOR MANUFACTURING HERBICIDES ONLY**

**ACTIVE INGREDIENT:**

Dicamba [3,6-dichloro-*o*-anisic acid] 98.9%

**OTHER INGREDIENTS:** 1.1%

**TOTAL:** 100.0%

**KEEP OUT OF REACH OF CHILDREN**  
**DANGER**

FIRST AID	
<b>If in eyes:</b>	<ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li><li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
<b>If swallowed:</b>	<ul style="list-style-type: none"><li>• Call a poison control center or doctor immediately for treatment advice.</li><li>• Have person sip a glass of water if able to swallow.</li><li>• Do not induce vomiting unless told to do so by the poison control center or doctor.</li><li>• Do not give anything by mouth to an unconscious person.</li></ul>
<b>If on skin or clothing:</b>	<ul style="list-style-type: none"><li>• Take off contaminated clothing.</li><li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
<b>NOTE TO PHYSICIAN:</b> Probable mucosal damage may contraindicate the use of gastric lavage.	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For information on this pesticide product (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Information Center at 1-800-858-7378, Monday through Friday, 9 a.m. to 5 p.m. After 5:00 p.m., call your poison control center at 1-800-222-1222.	

EPA Reg. No. 9468-45

EPA Est. No.

Net Contents: See container

**Manufactured for:**

Ritter Chemical, LLC

P. O. Box 430974

Houston, TX 77243

(713) 461-2262

**PRECAUTIONARY STATEMENTS**  
**HAZARDS TO HUMANS AND DOMESTIC ANIMALS**

**DANGER.** Corrosive. Causes irreversible eye damage. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Wear goggles or face shield when handling. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

**ENVIRONMENTAL HAZARDS**

Do not contaminate water by the cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge

Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. This product may only be used to formulate herbicide products for the following use(s):

1. Asparagus, corn, fallow systems, grass forage, fodder and hay (including grasses grown for seed), millet, small grains (barley, oats, wheat), sorghum (including sudangrass), soybeans, sugarcane, cotton, pasture and rangeland, Conservation Reserve Program Areas, farmsteads, fence rows, lawns, non-irrigation ditchbanks, rights-of-way, roadsides, turf and sod farms;
2. Uses for which EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration.
3. Uses for experimental purposes that are in compliance with EPA registration for the formulated products.

This product may be used to formulate products for specific uses not listed on the label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding support of such uses.

Each formulator is responsible for obtaining EPA registration for their end-use product(s).

**STORAGE AND DISPOSAL**

Do not contaminate water, food or feed by storage or disposal.

**PESTICIDE STORAGE:** Store in original container, in a well-ventilated area away from fertilizers, feed and foodstuffs. Avoid cross-contamination with other pesticides. Spillage or leakage should be contained, carefully swept up, and collected for disposal. Wash area of spill with detergent and water.

**PESTICIDE DISPOSAL:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**CONTAINER DISPOSAL: Plastic Bag:** Nonrefillable container. Do not reuse or refill this container. Completely empty bag into formulation equipment. Then offer for recycling if available, or dispose of empty bag in a sanitary landfill or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

**WARRANTY AND LIABILITY**

Ritter Chemical LLC warrants that this product conforms to the chemical description on the label, and is reasonably fit for the purposes set forth in the "Complete Directions for Use" booklet labeling, when used in accordance with those Complete Directions for Use, under the conditions described therein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, NO OTHER EXPRESS WARRANTY OR IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE OR MERCHANTABILITY IS MADE. This warranty is also subject to the conditions and limitation stated herein.

[20111003]



# Material Sent for Data Extraction

Reg # 9468-45

Description: New Product

☒ Material(s) Sent to Data Extraction Contractors:

☒ New Stamped Label Dated 10/3/11

☐ Notification Dated \_\_\_\_\_

☐ New CSF(s) Dated \_\_\_\_\_

☐ Other: \_\_\_\_\_

☒ Decision #: 446591

☐ Other Action/Comments: \_\_\_\_\_

Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer: James Stone

Phone: 305-7391 Division: RD/HB

Date: 10/3/11



U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Registration Division (7505P)  
1200 Pennsylvania Ave., NW  
Washington, D.C. 20460

EPA Reg.

Number:

9468-45

Date of Issuance:

OCT - 3 2011

NOTICE OF PESTICIDE:

☒ Registration  
☐ Reregistration  
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Ritter Dicamba Technical

Name and Address of Registrant (include ZIP Code):

Ritter Chemical LLC  
c/o Pyxis Regulatory Consulting, Inc.  
4110 136<sup>th</sup> ST. NW  
Gig Harbor, WA 98332

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA sec. 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product when the Agency requires all registrants of similar products to submit data.
2. Add the phrase "EPA Reg. No. 9468-45" to your label before you release the product for shipment.

Signature of Approving Official:

Date:

Kathryn V. Montague  
Product Manager 23  
Herbicide Branch  
Registration Division (7505P)

OCT - 3 2011

page 2

EPA Reg. No. 9468-45

3. Submit one (1) copy of your final printed labeling before you release the product for shipment.

4. Submit the results of one year storage stability and corrosion characteristic studies to EPA within one year of this date of registration. Submit a hard copy and an electronic copy also.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

# Ritter Dicamba Technical

## FOR MANUFACTURING HERBICIDES ONLY

**ACTIVE INGREDIENT:**

Dicamba [3,6-dichloro-*o*-anisic acid] .....98.9%

**OTHER INGREDIENTS:** .....1.1%

**TOTAL:** .....100.0%

### KEEP OUT OF REACH OF CHILDREN

### DANGER

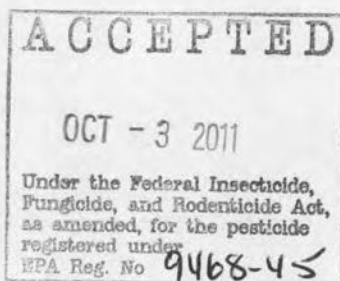
FIRST AID	
<b>If in eyes:</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>If swallowed:</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by the poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
<b>If on skin or clothing:</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>NOTE TO PHYSICIAN:</b> Probable mucosal damage may contraindicate the use of gastric lavage. Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For information on this pesticide product (including health concerns, medical emergencies, or pesticide incidents), call the National Pesticide Information Center at 1-800-858-7378, Monday through Friday, 9 a.m. to 5 p.m. After 5:00 p.m., call your poison control center at 1-800-222-1222.	

See back panel for additional precautionary statements.

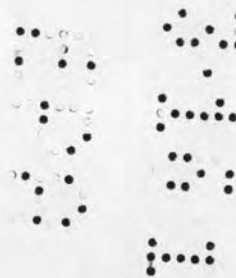
EPA Reg. No. 9468-  
EPA Est. No.

**Manufactured for:**  
Ritter Chemical, LLC  
P. O. Box 430974  
Houston, TX 77243  
(713) 461-2262

Net Contents:



**Batch No.:**





## PRECAUTIONARY STATEMENTS

### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

**DANGER.** Corrosive. Causes irreversible eye damage. Harmful if swallowed. Do not get in eyes, on skin or on clothing. Wear goggles or face shield when handling. Wash thoroughly with soap and water after handling. Remove contaminated clothing and wash before reuse.

### ENVIRONMENTAL HAZARDS

Do not contaminate water by the cleaning of equipment or disposal of wastes. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

### DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product may only be used to formulate herbicide products for the following use(s):

1. Asparagus, corn, fallow systems, grass forage, fodder and hay (including grasses grown for seed), millet, small grains (barley, oats, wheat), sorghum (including sudangrass), soybeans, sugarcane, cotton, pasture and rangeland, Conservation Reserve Program Areas, farmsteads, fence rows, lawns, non-irrigation ditchbanks, rights-of-way, roadsides, turf and sod farms;
2. Uses for which EPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration.
3. Uses for experimental purposes that are in compliance with EPA registration for the formulated products.

This product may be used to formulate products for specific uses not listed on the label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding support of such uses.

Each formulator is responsible for obtaining EPA registration for their end-use product(s).

### STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

**PESTICIDE STORAGE:** Store in original container, in a well-ventilated area away from fertilizers, feed and foodstuffs. Avoid cross-contamination with other pesticides. Spillage or leakage should be contained, carefully swept up, and collected for disposal. Wash area of spill with detergent and water.

**PESTICIDE DISPOSAL:** Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

**CONTAINER DISPOSAL: Plastic Bag:** Nonrefillable container. Do not reuse or refill this container. Completely empty bag into formulation equipment. Then offer for recycling if available, or dispose of empty bag in a sanitary landfill or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

### WARRANTY AND LIABILITY

Ritter Chemical LLC warrants that this product conforms to the chemical description on the label, and is reasonably fit for the purposes set forth in the "Complete Directions for Use" booklet labeling, when used in accordance with those Complete Directions for Use, under the conditions described therein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, NO OTHER EXPRESS WARRANTY OR IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE OR MERCHANTABILITY IS MADE. This warranty is also subject to the conditions and limitation stated herein.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

**FEE**

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS  
REGISTRATION DIVISION (7505P)

**BARCODE:** 388021; **Reg. No. /FILE SYMBOL No.:** 9468-UL; **PRODUCT:** Ritter Dicamba Technical

**DATE:** August 25, 2011

**SUBJECT:** Product Chemistry Review of "Ritter Dicamba Technical" TGA/MUP

**FROM:** Akiva Abramovitch, Ph.D.  
Technical Review Branch / RD (7505P)

*[Handwritten signature]* *[Handwritten signature]* 9/7/11

**TO:** James Stone, Team Reviewer /Kathryne Montague, Risk Manager, RM 23  
Herbicide Branch / RD (7505P)

**DP BARCODE:** 388021

**DECISION No.:** 446591

**REGISTRATION NO./FILE SYMBOL NO.:** 9468-UL

**PRODUCT NAME:** Ritter Dicamba Technical

**PC CODE:** 028801

**REGISTRANT:** Ritter Chemicals, LLC

**USE:** Herbicide

**FOOD USE:** Yes ☒ No ☐

**MRID Numbers:** 484205-01 through 484205-04

**INTRODUCTION:**

The registrant is seeking a new product registration for Ritter Dicamba Technical. The product is substantially similar (identical?) to a currently registered product [REDACTED] and the registrant is using the "cite-all" method of support. A basic formulation dated 9/6/11 (replaces the 3/11/11 CSF) was submitted as well as Group A data.

This review has been altered subsequent to the contractor's signatures.

**SUMMARY OF FINDINGS:**

1. The registrant submitted a Confidential Statement of Formula (CSF) for the basic formulation (3/11/2011). The product chemistry data corresponding to guideline reference 830.1550 (product identity & composition) submitted on the CSF satisfy the data requirements of 40CFR§158.155. The data corresponding to guideline reference 830.1750 (certified limits) satisfy the requirements of 40CFR§158.175 [MRID No. 484205-01]. The content of active ingredient given on the CSF for the basic formulation matches the label.
2. The product chemistry data submitted corresponding to guideline reference 830.1600 (description of material used to produce the product) satisfy the data requirements of 40CFR§ 158.160 [MRID No. 484205-01].
3. The product chemistry data submitted corresponding to guideline reference 830.1620 (description of production process) satisfy the data requirements for 40CFR§158.162 [MRID No. 484205-01].

\*Product ingredient source information may be entitled to confidential treatment\*



4. The product chemistry data submitted corresponding to guideline reference 830.1670 (discussion of the formation of impurities) satisfy the data requirements for 40CFR§158.167 [MRID No. 484205-01].
5. The product chemistry data submitted corresponding to guideline reference 830.1700 (preliminary analysis) to support the claims on the CSF satisfy the data requirements of 40CFR§158.170 [MRID No. 484205-02].
6. The product chemistry data submitted corresponding to guideline reference 830.1800 (enforcement analytical method) satisfy the data requirements of 40CFR§158.180 [MRID 484205-02].
7. The data submitted corresponding to guidelines 830 Series Subgroup B (physical-chemical properties) satisfy the data requirements of 40CFR§158.190 [MRID No. 484205-03 and 484205-04]. Waivers were requested for explodability and flammability. Provision of corrosion characteristics and storage stability will be conducted if requested by the Agency.

#### **CONCLUSIONS:**

The TRB has reviewed the product chemistry data submitted for Ritter Dicamba Technical (produced by Ritter Chemicals, LLC) and has concluded that:

1. The product chemistry data submitted for guideline 830 Series group A are acceptable, except for impurities of potential concern.
2. The product chemistry data corresponding to 830 series group B (physical-chemical properties) are acceptable.
3. The proposed CSF for the basic formulation dated September 6, 2011 (replaces the March 11, 2011 CSF) is acceptable. The registrant listed all the known potential impurities of toxicological concern on the CSF. The total amount of unidentified impurities is at [REDACTED]
4. This product is substantially similar to product [REDACTED]. However, this product listed all potential toxic impurities on the CSF not listed on the "me-too" CSF. This product also has a higher percentage of unidentified residues [REDACTED] but none above 0.1%.

#### 830.1550. Product identity & composition: (MRID No. 484205-01)

Common Name: Dicamba

Chemical name (CAS): 3,6-dichloro-2-methoxybenzoic acid

(IUPAC): 3,6-dichloro-*o*-anisic acid

CAS No.: 1918-00-9

PC Code No.: 028801

Empirical Formula: C<sub>8</sub>H<sub>6</sub>O<sub>3</sub>Cl<sub>2</sub>

Molecular Weight: 221.0

Structural Formula:

\*Product ingredient source information may be entitled to confidential treatment\*

\*Manufacturing process information may be entitled to confidential treatment\*

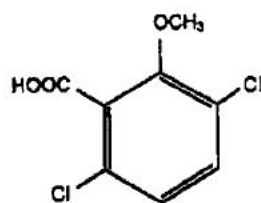


Table 1. Manufacturing and Impurity Data for Ritter Dicamba Technical TGA1				
GLN	Requirement	MRID	Status	Details and /or Deficiency
830.1550	Product Identity and composition	484205-01	A	CSF
830.1600	Description of materials used to produce the product	484205-01	A	
830.1620	Description of production process	484205-01	A	
830.1670	Discussion of formation of impurities	484205-01	U	potential impurities of toxicological concern were not identified or discussed.
830.1700	Preliminary analysis	484205-02	A	
830.1750	Certified limits	484205-01	A	
830.1800	Enforcement analytical method	484205-02	A	CSF
A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress ; U = Up-grade (additional information required);				

\*Manufacturing process information may be entitled to confidential treatment\*



830 Series Subgroup B (Physical-Chemical Properties)

Table 2: Physical and Chemical Properties of: Ritter Dicamba Technical TGA1				
GLN	Requirement	MRID	Status	Result or Deficiency
830.6302	Color	484205-03	A	Off-white with brown specks
830.6303	Physical state	484205-03	A	Solid crystals
830.6304	Odor	484205-03	A	Odorless
830.6313	Stability to normal and elevated temperatures, metals, and metal ions	484205-03	A	Stable to normal and elevated temperatures for 14 days
830.6314	Oxidation/reduction: chemical incompatibility	484205-03	A	Compatible with water, hexane, zinc, $\text{NH}_4\text{H}_2\text{PO}_4$ , and $\text{KMnO}_4$ .
830.6315	Flammability	484205-04, CSF	W	Solid; contains no flammable components
830.6316	Explosibility	484205-04	W	Solid; does not contain any explosive components
830.6317	Storage stability	484205-04	G	Will be conducted if requested by Agency
830.6319	Miscibility	484205-04	N/A	Not an emulsifiable liquid
830.6320	Corrosion characteristics	484205-04	G	Will be conducted if requested by Agency
830.7000	pH	484205-03	A	$1.92 \pm 0.03$ at $25.7^\circ\text{C}$
830.7050	UV/Visible absorption	484205-03	A	Wavelength; molar absorption: Acid: $\lambda_{\text{max}} = 281.0$ ; $\epsilon_{\text{max}} = 776$ Neutral: $\lambda_{\text{max}} = 275.2$ ; $\epsilon_{\text{max}} = 490.3$ Basic: $\lambda_{\text{max}} = 275.$ ; $\epsilon_{\text{max}} = 469.7$
830.7100	Viscosity	484205-04	N/A	Solid
830.7200	Melting point	484205-03	A	$\sim 114.5 - 116.1^\circ\text{C}$
830.7220	Boiling point	484205-04	N/A	Solid
830.7300	Density	484205-03	A	$0.702996 \pm 0.000488$ g/mL at $19^\circ\text{C}$
830.7370	Dissociation constants in water (DC)	484205-04	A	$\text{pK}_a = 1.97$ (Tomlin, The Pesticide Manual, 13 <sup>th</sup> Edition, p. 279, BCPC Publications, Hampshire, 2003)
830.7550	Partition coefficient (o/w)	484205-04	A	$\text{Log } P = -0.55$ (pH 5); $-1.88$ (pH 6.8); $-1.9$ (pH 8.9) (Tomlin, The Pesticide Manual, 13 <sup>th</sup> Edition, p. 279, BCPC Publications, Hampshire, 2003)
830.7840	Water solubility	484205-04	A	6.1 g/L at $25^\circ\text{C}$ (Tomlin, The Pesticide Manual, 13 <sup>th</sup> Edition, p. 279, BCPC Publications, Hampshire, 2003)
830.7950	Vapor pressure	484205-04	A	1.67 mPa at $25^\circ\text{C}$ (Tomlin, The Pesticide Manual, 13 <sup>th</sup> Edition, p. 279, BCPC Publications, Hampshire, 2003)
A = Acceptable; N = unacceptable (see Deficiency); N/A = Not Applicable; G = Data gap; I = In progress ; U = Up-grade (additional information required); W = waivers				

830.1800 (enforcement analytical method)

The enforcement analytical method to determine the content of active ingredient is HPLC with UV detection. Appropriate validation and precision studies were conducted and sample chromatograms were provided. The registrant provided the following details in MRID 484205-01:

Ritter Dicamba Technical is dissolved in acetonitrile and separated on a ZORBAX XDB C8 reverse phase column. The content of dicamba is measured by an HPLC-UV detector with an external standard.

#### Apparatus

HPLC System:	Agilent 1100 HPLC
Glassware:	volumetric
Balance:	Mettler Toledo XS 205
Vials:	2 ml

#### Reagents

Dicamba standard:	known purity
Phosphoric Acid:	analytical grade
Acetonitrile:	HPLC grade
Water	redistilled

#### Chromatographic Conditions

Conditions may be changed to obtain satisfactory performance with other instruments provided adequate resolution and sensitivity are achieved.

Instrument:	Agilent 1100 HPLC
HPLC column:	ZORBAX XDB C8 150 x 4.6 mm, 5 micron
Mobile phase:	Acetonitrile/phosphoric acid aqueous solution (pH=3), 35:65
Column temperature:	25°C
Injection volume:	3 µl
Stop time:	8 minutes
Flow rate:	1.0 ml/min.
Wavelength:	230 nm
Retention time:	dicamba, ~ 5.3 minutes

## DATA EVALUATION RECORD

### DICAMBA (RITTER DICAMBA TECHNICAL)

**STUDY TYPES:** Product Identity and Composition (OPPTS 830.1550)  
Description of Materials Used to Produce the Product (OPPTS 830.1600)  
Description of the Production Process (OPPTS 830.1620)  
Discussion of Formation of Impurities (OPPTS 830.1670)  
Preliminary Analysis (OPPTS 830.1700)  
Certified Limits (OPPTS 830.1750)  
Enforcement Analytical Method (OPPTS 830.1800)  
Physical and Chemical Characteristics (OPPTS 830.6302-830.7950)

**MRIDs 484205-01 through 484205-04**

Prepared for  
Registration Division  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202

Prepared by  
Summitec Corporation  
9724 Kingston Pike, Suite 602  
Knoxville, Tennessee  
Task Order No. 3-A-98

Primary Reviewer:  
Thomas C. Marshall, Ph.D

Signature: Thomas C. Marshall, AE  
Date: AUG 22 2011

Secondary Reviewers:  
Dennis Opresko, Ph.D

Signature: Dennis Opresko  
Date: AUG 22 2011

Robert Ross, M.S., Program Manager

Signature: Robert H. Ross  
Date: AUG 22 2011

Quality Assurance:  
Angie Edmonds, B.S.

Signature: Angie Edmonds  
Date: AUG 22 2011

#### Disclaimer

his review may have been altered subsequent to the contractor's signatures above.  
Summitec Corp. for the U.S. Environmental Protection Agency under Contract No.EP-W-11-014



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND  
POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS  
REGISTRATION DIVISION (7505P)

**TECHNICAL REVIEW BRANCH  
SIMILARITY DETERMINATION**

01/SEP/2011

MEMORANDUM

Subject: Name of Pesticide Product: Ritter Dicamba Technical  
EPA Reg. No. /File Symbol: 9468-UL  
DP Barcode: D388022  
Decision No: 446591  
Action Code: R310  
PC Code: 029801 (dicamba)

From: Eugenia McAndrew, Biologist  
Technical Review Branch  
Registration Division (7505P)

*E. McAndrew*  
*Harlin*  
*Toxicologist*

To: James Stone, RM Team 23  
Herbicide Branch  
Registration Division (7505P)

Applicant: Ritter Chemicals, LLC  
P.O. Box 430974  
Houston, TX 77243

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Dicamba	98.9

<u>Other Ingredient(s):</u>	<u>1.1</u>
Total:	100.0%



**ACTION REQUESTED:** The Risk Manager requests: For Similarity Clinic: "Under the Cite-All Method is the acute toxicity substantially similar to the cited me too product [REDACTED]"

**BACKGROUND:** Ritter Chemicals, LLC has applied for registration of Ritter Dicamba Technical, EPA File Symbol 9468-UL, claiming similarity to [REDACTED]

[REDACTED] Both products are technical grade for manufacturing use only. The registrant is using the cite-all method of data support to satisfy the acute toxicity data requirements. A basic CSF dated March 11, 2011, a label and company letter are included in the submission.

A search of the OPP electronic databases [REDACTED]  
[REDACTED]

#### RECOMMENDATIONS:

1. TRB compared the formulations of the proposed product, 9468-UL and the cited product, [REDACTED] and concluded that the two products are substantially similar.
2. The acute toxicity profile for the proposed product, Ritter Dicamba Technical, EPA File Symbol 9468-UL, is as follows:

acute oral toxicity	III	cited
acute dermal toxicity	IV	cited
acute inhalation toxicity	IV	cited
primary eye irritation	I	cited
primary skin irritation	IV	cited
dermal sensitization	negative	cited

3. This memorandum pertains only to the decision concerning whether the subject product is similar to the cited product from an acute toxicological view point. For the purposes of this action, TRB has made no further determination of the adequacy of the toxicological data base or the precautionary label of the cited product.
4. The proposed basic CSF submitted for 9468-UL must be accepted by the TRB Product Chemistry Team.

\*Product ingredient source information may be entitled to confidential treatment\*

**LABELING:** Based on the toxicity profile above, the following are the precautionary and first aid statements for this product as obtained from the Label Review System:

**PRODUCT ID #:** 009468-00045

**PRODUCT NAME:** Ritter Dicamba Technical

**PRECAUTIONARY STATEMENTS**

**SIGNAL WORD:** DANGER

**Hazards to Humans and Domestic Animals:**

Corrosive. Causes irreversible eye damage. Harmful if swallowed. Do not get in eyes or on clothing. Wear protective eyewear (goggles, face shield, or safety glasses).

**First Aid:**

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

**Note to Physician:** Probable mucosal damage may contraindicate the use of gastric lavage.

**User Safety Recommendations:**

Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

PYXIS REGULATORY CONSULTING, INC.

484205-00

4110 136<sup>th</sup> St. NW  
Gig Harbor, WA 98332

Phone: 253-853-7369  
Fax: 253-853-5516  
www.PyxisRC.com

March 11, 2011

OVERNIGHT DELIVERY

Kathryn Montague (PM 23)  
Document Processing Desk (REGFEE)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202

RE: Ritter Chemical, LLC  
Ritter Dicamba Technical (EPA File Symbol 9468- )  
Application for New Pesticide Registration  
PRIA category R310 (46: New manufacturing use product)

Dear Ms. Montague,

On behalf of Ritter Chemical, LLC, we are submitting an application for registration of Ritter Dicamba Technical. In support of this application, we submit the following documents:

1. Application for a New Pesticide Registration (EPA Form 8570-1)
2. Confidential Statement of Formula (EPA Form 8570-4)
3. Three (3) Copies of the Proposed Labeling
4. A CD containing an electronic version of the proposed labeling
5. Certification with Respect to Label Integrity
6. Certification with Respect to Citation of Data (EPA Form 8570-34)
7. Agency Internal Use Copy of the Data Matrix
8. Public File Copy of the Data Matrix
9. Copy of PRIA payment
10. Letter of Authorization
11. Product Specific Data (3 copies of each report):

48420501	Volume 1	830.1550, 830.1600, 830.1620, 830.1650, 830.1670, 830.1750, 830.1800	Tillman, A. M. Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Description of the Formulation Process, Discussion of the Formation of Impurities, Certified Limits, and Enforcement Analytical Method for Ritter Dicamba Technical. <i>Contains Confidential Business Information.</i>
48420502	Volume 2	830.1700, 830.1800	Li, H. Preliminary Analysis and Enforcement Analytical Method of Dicamba TGAI. <i>Contains Confidential Business Information.</i>

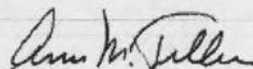


<b>48420503</b>	Volume 3	830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.7000, 830.7050, 830.7200, 830.7300	Weller, P. J. Group B Product Chemistry Analysis of Dicamba Technical.
<b>48420504</b>	Volume 4	830.6313, 830.6315, 830.6316, 830.6317, 830.6319, 830.6320, 830.6321, 830.7100, 830.7220, 830.7300, 830.7370, 830.7520, 830.7550-7570, 830.7840-7860, 830.7950	Tillman, A. M. Ritter Dicamba Technical Waiver Requests for Certain Phys-Chem Properties.

We would like to note that Ritter Chemical, LLC is using the cite-all method of support. As per EPA's interpretations of 40 CFR Parts 152.86(b)(2)(i) and 152.93(b)(2)(i), Ritter Chemical, LLC submitted notices of intent to apply and offers to pay to all companies on the September 30, 2010 Data Submitter's List. This action falls under PRIA category R310 (46: New manufacturing use product) because it is an application for registration for a manufacturing use product identical to a currently registered product. The PRIA fee for this action is \$4,807 and has been paid. The decision timeline is 6 months.

We trust you will find this application complete. However, please feel free to contact me ((253) 853-7369, [Ann@PyxisRC.com](mailto:Ann@PyxisRC.com)) if you have any questions or need any additional information.

Sincerely,



Ann M. Tillman

Enclosures





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

(Jim King)

File  
com

March 28, 2011

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

OPP Decision Number: D-446591  
EPA File Symbol or Registration Number: 9468-UL  
Product Name: RITTER DICAMBA TECHNICAL  
EPA Receipt Date: 16-Mar-2011  
EPA Company Number: 9468  
Company Name: RITTER CHEMICAL, LLC

Ann Tillman  
PYXIS REGULATORY CONSULTING, INC.  
RITTER CHEMICAL, LLC  
4110 136TH STREET, N.W.,  
GIG HARBOR, WA 98332-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action previously identified as R300 has been reclassified identified as Action Code: R310

NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT  
CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY);

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee  
Ombudsman at (703) 308-9362.

Sincerely,  
Front End Processing Staff  
Information Technology & Resources Management Division

*Jim Stron*



**Fw: Ritter Dicamba Technical 9468-UL PRIA Category**

Stephen Schaible to: John Jamula, Teresa Downs

03/25/2011 04:40 PM

JJ,

Please recode this action as an R310. Thanks! Steve

Stephen A. Schaible  
U.S. Environmental Protection Agency  
Office of Pesticide Programs  
Registration Division (7505P)  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460  
ph: (703)308-9362  
fax: (703)305-6920

----- Forwarded by Stephen Schaible/DC/USEPA/US on 03/25/2011 04:39 PM -----

From: Ann Tillman <Ann@PyxisRC.com>  
To: Stephen Schaible/DC/USEPA/US@EPA  
Cc: Teresa Downs/DC/USEPA/US@EPA  
Date: 03/24/2011 10:38 AM  
Subject: RE: Ritter Dicamba Technical 9468-UL PRIA Category

Thanks, Steve. This application is not a 100% repack.

Ann

-----Original Message-----

From: Schaible.Stephen@epamail.epa.gov [mailto:Schaible.Stephen@epamail.epa.gov]  
Sent: Thursday, March 24, 2011 10:32 AM  
To: Ann Tillman  
Cc: Downs.Teresa@epamail.epa.gov  
Subject: Re: Ritter Dicamba Technical 9468-UL PRIA Category

Hi Ann,

At face value, I would absolutely agree. The only situation where a technical would qualify as a R300 would be if it is a 100% repack. It sounds like this was a coding error on our end, and I'll follow up with Teresa and JJ to make sure this is the case.

Thanks for bringing this to my attention! In all likelihood this would have been caught once it got to the PM, but you are getting clarity earlier in the process this way.

Regards, Steve

Stephen A. Schaible  
U.S. Environmental Protection Agency  
Office of Pesticide Programs  
Registration Division (7505P)  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460  
ph: (703)308-9362  
fax: (703)305-6920

From: Ann Tillman <Ann@PyxisRC.com>  
To: Stephen Schaible/DC/USEPA/US@EPA  
Date: 03/24/2011 06:53 AM  
Subject: Ritter Dicamba Technical 9468-UL PRIA Category

Hi, Steve,

I received this letter (attached) in the mail but I really don't believe that the PRIA category should be R300. Every application for registration of a me-too technical has typically been R310. Is there something different about this application that makes it an R300?

Ann

Ann M. Tillman, Ph.D.  
Pyxis Regulatory Consulting, Inc.  
4110 136th St. NW  
Gig Harbor, WA 98332  
Office (253) 853-7369  
Fax (253) 853-5516  
Email Ann@PyxisRC.com  
[attachment "20110317 9468-UL PRIA reclassification.pdf" deleted by Stephen Schaible/DC/USEPA/US]

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060. Approval expires 2-28-95

 <b>United States</b> <b>Environmental Protection Agency</b> Washington, DC 20460	<input checked="" type="checkbox"/> <b>Registration</b> <input type="checkbox"/> <b>Amendment</b> <input type="checkbox"/> <b>Other</b>	OPP Identifier Number
---	---	-----------------------

### Application for Pesticide - Section I

<b>1. Company/Product Number</b> 9468- <u>LL</u>	<b>2. EPA Product Manager</b> K. Montague	<b>3. Proposed Classification</b> <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
<b>4. Company/Product (Name)</b> Ritter Chemicals, LLC/Ritter Dicamba Technical	<b>PM#</b> 23	
<b>5. Name and Address of Applicant (Include ZIP Code)</b> Ritter Chemicals, LLC c/o Pyxis Regulatory Consulting, Inc. 4110 136th St. NW Gig Harbor, WA 98332 <input type="checkbox"/> Check if this is a new address		<b>6. Expedited Review.</b> In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. <span style="background-color: black; color: black;">XXXXXXXXXX</span> Product Name <span style="background-color: black; color: black;">XXXXXXXXXX</span>

### Section - II

<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input checked="" type="checkbox"/> "Me Too" Application. <input type="checkbox"/> Other - Explain below.
---	--

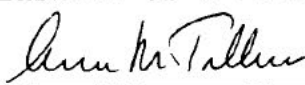
**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

This application falls under Category R310 (46: New manufacturing use product) because it is an application for registration for a new technical product identical in composition to a currently registered product. The fee which is due is \$4,807.00 and has been paid. The decision timeline is 6 months.

### Section - III

<b>1. Material This Product Will Be Packaged In:</b>			
<b>Child-Resistant Packaging</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<b>Unit Packaging</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<b>Water Soluble Packaging</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<b>2. Type of Container</b> <input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) <u>Polypropylene woven bags</u>
<b>* Certification must be submitted</b>		If "Yes" Unit Packaging wgt.    No. per container If "Yes" Package wgt.    No. per container	
<b>3. Location of Net Contents Information</b> <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		<b>4. Size(s) Retail Container</b> 800 kg	<b>5. Location of Label Directions</b> <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product
<b>6. Manner in Which Label is Affixed to Product</b> <input checked="" type="checkbox"/> Lithograph Paper glued Stenciled <input type="checkbox"/> Other _____			

### Section - IV

<b>1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)</b>			
<b>Name</b> Pyxis Regulatory Consulting, Inc.	<b>Title</b> Agent	<b>Telephone No. (Include Area Code)</b> (253)-853-7369	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			<b>6. Date Application Received (Stamped)</b>     
<b>2. Signature</b> 	<b>3. Title</b> Agent		
<b>4. Typed Name</b> Ann M. Tillman	<b>5. Date</b> 3/11/11		





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**WASHINGTON, D.C. 20460**

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**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number Ritter Chemicals, LLC c/o Pyxis Regulatory 4110 136th St. NW Gig Harbor, WA 253- 853-7369	EPA Registration Number/File Symbol 9468-
Active Ingredient(s) and/or representative test compound(s) Dicamba	Date 3/11/11
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Terrestrial food/feed, Terrestrial Non-food, Residential Outdoor	Product Name Ritter Dicamba Technical

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT** (Check one method only)

<input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).	<input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).
--	---

**SECTION II: GENERAL OFFER TO PAY**

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature <i>Ann M. Tillman</i>	Date 3/11/11	Typed or Printed Name and Title Ann M. Tillman, Agent
------------------------------------	-----------------	--


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## DATA MATRIX


Date March 7, 2011			EPA Reg. No./File Symbol 9468-		Page 1 of 7
Applicant's/Registrant's Name & Address Ritter Chemical, LLC P.O. Box 430974 Houston, TX 77243			Product Ritter Dicamba Technical		
Ingredient Dicamba (CAS No. 1918-00-9)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<b>Product Specific Data Requirements</b>					
830.1550	Product Identity and Composition	Volume 1	Ritter Chemical, LLC	OWN	
830.1600	Description of Materials Used to Produce the Product	Volume 1	Ritter Chemical, LLC	OWN	
830.1620	Description of Production Process	Volume 1	Ritter Chemical, LLC	OWN	
830.1650	Description of Formulation Process				Not required <sup>1</sup>
830.1670	Discussion of Formation of Impurities	Volume 1	Ritter Chemical, LLC	OWN	
830.1700	Preliminary Analysis	Volume 2	Ritter Chemical, LLC	OWN	
830.1750	Certified Limits	Volume 1	Ritter Chemical, LLC	OWN	
830.1800	Enforcement Analytical Method	Volume 1	Ritter Chemical, LLC	OWN	
		Volume 2	Ritter Chemical, LLC	OWN	
830.6302	Color	Volume 3	Ritter Chemical, LLC	OWN	
830.6303	Physical State	Volume 3	Ritter Chemical, LLC	OWN	
830.6304	Odor	Volume 3	Ritter Chemical, LLC	OWN	
Signature 			Name and Title Ann M. Tillman, Consultant		Date March 7, 2011

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## DATA MATRIX

Date March 7, 2011			EPA Reg. No./File Symbol 9468-		Page 2 of 7
Applicant's/Registrant's Name & Address Ritter Chemical, LLC P.O. Box 430974 Houston, TX 77243			Product Ritter Dicamba Technical		
Ingredient Dicamba (CAS No. 1918-00-9)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	Volume 3 Volume 4	Ritter Chemical, LLC Ritter Chemical, LLC	OWN OWN	Data Waiver <sup>2</sup>
830.6314	Oxidation/Reduction: Chemical Incompatibility	Volume 3	Ritter Chemical, LLC	OWN	
830.6315	Flammability	Volume 4	Ritter Chemical, LLC	OWN	Waiver <sup>3</sup>
830.6316	Explosibility	Volume 4	Ritter Chemical, LLC	OWN	Waiver <sup>4</sup>
830.6317	Storage Stability	Volume 4	Ritter Chemical, LLC	OWN	PRN 92-5 <sup>5</sup>
830.6319	Miscibility	Volume 4	Ritter Chemical, LLC	OWN	Waiver <sup>6</sup>
830.6320	Corrosion Characteristics	Volume 4	Ritter Chemical, LLC	OWN	PRN 92-5 <sup>5</sup>
830.6321	Dielectric Breakdown Voltage	Volume 4	Ritter Chemical, LLC	OWN	Not required <sup>7</sup>
830.7000	pH	Volume 3	Ritter Chemical, LLC	OWN	
830.7050	UV/Visible Absorption	Volume 3	Ritter Chemical, LLC	OWN	
830.7100	Viscosity	Volume 4	Ritter Chemical, LLC	OWN	Not required <sup>7</sup>
830.7200	Melting Point/Melting Range	Volume 3	Ritter Chemical, LLC	OWN	
830.7220	Boiling Point/Boiling Range	Volume 4	Ritter Chemical, LLC	OWN	Not required <sup>8</sup>
Signature 			Name and Title Ann M. Tillman, Consultant		Date March 7, 2011


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## DATA MATRIX

Date March 7, 2011			EPA Reg. No./File Symbol 9468-		Page 3 of 7
Applicant's/Registrant's Name & Address Ritter Chemical, LLC P.O. Box 430974 Houston, TX 77243			Product Ritter Dicamba Technical		
Ingredient Dicamba (CAS No. 1918-00-9)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7300	Density/Relative Density/Bulk Density	Volume 3	Ritter Chemical, LLC	OWN	See endnote <sup>9</sup>
830.7370	Dissociation Constants in Water	Volume 4	Ritter Chemical, LLC	PL	
830.7520	Particle Size, Fiber Length, and Diameter Distribution	Volume 4	Ritter Chemical, LLC	OWN	Waiver <sup>10</sup>
830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method	Volume 4	Ritter Chemical, LLC	PL	
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method				See 830.7550
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography				See 830.7550
830.7840	Water Solubility: Column Elution Method; Shake Flask Method	Volume 4	Ritter Chemical, LLC	PL	
830.7860	Water Solubility, Generator Column Method				See 830.7840
830.7950	Vapor Pressure	Volume 4	Ritter Chemical, LLC	PL	
Signature 			Name and Title Ann M. Tillman, Consultant		Date March 7, 2011

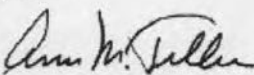


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## DATA MATRIX


Date March 7, 2011			EPA Reg. No./File Symbol 9468-		Page 4 of 7
Applicant's/Registrant's Name & Address Ritter Chemical, LLC P.O. Box 430974 Houston, TX 77243			Product Ritter Dicamba Technical		
Ingredient Dicamba (CAS No. 1918-00-9)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.1100	Acute Oral Toxicity: Rat	Cite-All		PAY	
870.1200	Acute Dermal Toxicity: Rat	Cite-All		PAY	
870.1300	Acute Inhalation Toxicity: Rat	Cite-All		PAY	
870.2400	Primary Eye Irritation: Rabbit	Cite-All		PAY	
870.2500	Primary Dermal Irritation	Cite-All		PAY	
870.2600	Dermal Sensitization	Cite-All		PAY	
<b>Dicamba Product Specific and Generic Data Requirements</b>					
Ritter Chemical, LLC is using the cite-all option to satisfy product specific and generic data requirements will make offers-to-pay to the following companies on the dicamba data submitters list of September 30, 2010.					
		Cite-All	Syngenta Crop Protection, Inc.	PAY	
		Cite-All	Nufarm Americas Inc.	PAY	
		Cite-All	BASF Corp.	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date March 7, 2011

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## DATA MATRIX


Date March 7, 2011			EPA Reg. No./File Symbol 9468-		Page 5 of 7
Applicant's/Registrant's Name & Address Ritter Chemical, LLC P.O. Box 430974 Houston, TX 77243			Product Ritter Dicamba Technical		
Ingredient Dicamba (CAS No. 1918-00-9)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	E. I. DuPont de Nemours and Co., Inc.	PAY	
		Cite-All	Bayer Environmental Science	PAY	
		Cite-All	Monsanto Co.	PAY	
		Cite-All	The Scotts Co.	PAY	
		Cite-All	PBI/Gordon Corp.	PAY	
		Cite-All	BASF Corp.	PAY	
		Cite-All	The Andersons Lawn Fertilizer Division	PAY	
		Cite-All	Chemisco	PAY	
		Cite-All	Loveland Products, Inc.	PAY	
		Cite-All	Albaugh, Inc.	PAY	
		Cite-All	Dow Agrosiences LLC	PAY	
		Cite-All	Spray Drift Task Force	PAY	
		Cite-All	W. Neudorff GmbH Kg	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date March 7, 2011

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## DATA MATRIX


Date March 7, 2011			EPA Reg. No./File Symbol 9468-		Page 6 of 7
Applicant's/Registrant's Name & Address Ritter Chemical, LLC P.O. Box 430974 Houston, TX 77243			Product Ritter Dicamba Technical		
Ingredient Dicamba (CAS No. 1918-00-9)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	Repar Corp.	PAY	
		Cite-All	Petro-Canada Lubricants Inc.	PAY	
		Cite-All	Gharda USA, Inc.	PAY	
		Cite-All	Nufarm, Inc.	PAY	
		Cite-All	Outdoor Residential Exposure Task Force	PAY	
		Cite-All	Agricultural Reentry Task Force	PAY	
		Cite-All	Bayer Advanced	PAY	
		Cite-All	FIFRA Endangered Species Task Force LLC	PAY	
		Cite-All	Residential Exposure Joint Venture	PAY	
		Cite-All	Agricultural Handlers Exposure Task Force	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date March 7, 2011

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## DATA MATRIX

Date March 7, 2011			EPA Reg. No./File Symbol 9468-		Page 7 of 7
Applicant's/Registrant's Name & Address Ritter Chemical, LLC P.O. Box 430974 Houston, TX 77243			Product Ritter Dicamba Technical		
Ingredient Dicamba (CAS No. 1918-00-9)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
		Cite-All	Libertas Now, Inc.	PAY	
		Cite-All	J. Oliver Products, LLC	PAY	
		Cite-All	Tacoma Ag, LLC	PAY	
		Cite-All	Gharda Generics, Inc.	PAY	
Signature 			Name and Title Ann M. Tillman, Consultant		Date March 7, 2011



## Endnotes for Data Matrix for Ritter Dicamba MUP

- 
- <sup>1</sup> **830.1650** - These data are not required for the registration of a technical product. See 830.1620 for production process information.
- <sup>2</sup> **830.6313** - Ritter Chemical, LLC requests a waiver from the stability to metal and metal ion portion of this data requirement. Ritter Chemical, LLC does not intend to package Dicamba Technical in metal containers, nor is Dicamba Technical expected to come into contact with metals or metal ions during its storage or use. Therefore, a waiver from the requirement of these data is requested. Dicamba Technical was found to be stable at normal and elevated temperatures (these data are reported separately and is part of this submission).
- <sup>3</sup> **830.6315** - Ritter Chemical, LLC requests a waiver from the requirement of this data requirement since Dicamba Technical is a solid and does not contain any ingredients that are flammable. Please refer to the Confidential Statement of Formula for Dicamba Technical.
- <sup>4</sup> **830.6316** - Ritter Chemical, LLC requests a waiver from this data requirement. Dicamba does not have the chemical bonds or functional groups associated with explosive chemicals.
- <sup>5</sup> **830.6317, 830.6320** - Per PR Notice 92-5, storage stability and corrosion characteristics data are not required to be submitted unless specifically requested by the Agency. Ritter Chemical, LLC has initiated these studies and will submit the final report when available.
- <sup>6</sup> **830.6319** - This data requirement is required when the MUP is an emulsifiable liquid and to be diluted with petroleum solvents. Ritter Dicamba Technical is not an end-use product. Therefore these data are not required for Ritter Dicamba Technical.
- <sup>7</sup> **830.6321, 830.7100** - Dielectric breakdown data are required if the product is an end-use product. This data requirement is not applicable Ritter Dicamba Technical. Viscosity is required for liquid products and is not applicable to the solid Ritter Dicamba Technical.
- <sup>8</sup> **830.7220** - This data requirement is not applicable to Ritter Dicamba Technical because it is a solid. Refer to guideline 830.7200 for melting point data.
- <sup>9</sup> **830.7300** - Ritter Chemical, LLC conducted bulk density with Ritter Dicamba Technical. The bulk density is 0.703 g/mL. The public literature density for dicamba acid is reported to be 1.488 (Ref. (Reference: Tomlin, "The Pesticide Manual", 13<sup>th</sup> Edition, p. 279, BCPC Publications, Hampshire, 2003). However, EPA documents (docket EPA-HQ-OPP-2005-0479-005) indicate that the relative density is 1.57 which was obtained from a technical material that was only 87% pure. EPA cited data from the 6/30/89 Reregistration Standard. The bulk density of the Ritter Dicamba Technical me-too technical dicamba acid must be similar to the value obtained for Ritter Dicamba Technical: Tacoma Ag, LLC's Dicamba Acid Technical, EPA Reg. No. 83520-8, is also a me-too of the same cited product (based on information in the Registration Jacket for 83520-8) and the bulk density of the Tacoma Ag, LLC's technical product is 0.608 g/mL (see MSDS in Attachment 1). The bulk density values for Ritter Dicamba Technical and Tacoma Ag LLC's technical are similar. Therefore, the bulk density for Ritter Dicamba Technical should not be compared to data in the public literature since that data is for relative density and from an 87% pure technical material.
- <sup>10</sup> **830.7520** - Ritter Chemical, LLC is seeking a waiver for this data requirement. Ritter Dicamba Technical is not a fibrous material nor is it water insoluble.

## R 300 and 301

New products must provide a bridging rationale document. The bridging document directs OPP to use a currently registered set of 6 acute toxicity data and label; instead of submitting product specific data.

Guideline No.	Acute toxicity (6 pack) Study Title	Cited	
		Yes	No
870.1100	Acute Oral (LD50)	X	
870.1200	Acute Dermal (LD50)	X	
870.1300	Acute Inhalation (LC50)	X	
870.2400	Acute Eye Irritation	X	
870.2500	Acute Dermal Irritation	X	
870.2600	Dermal Sensitization	X	

Efficacy - which guideline depends on the proposed label use and they must cite the data to be used for the bridging rationale.

Guideline No.	Efficacy Study Titles	Cited		Comments
		Yes	No	
810.3100	Soil Treatments for Imported Fire Ants			NA
810.3200	Livestock, Poultry, Fur and Wool-Bearing Animal Treatments			NA
810.3300	Treatments to Control Pests of Humans and Pets			NA
810.3400	Mosquito, Black Fly, and Biting Midge (Sand Fly) Treatments			NA
810.3500	Premises Treatments			NA
810.3600	Structural Treatments			NA
810.3800	Methods for Efficacy Testing of Termite Baits			NA

# R 300 and 301

100% identical (repack): YES or (NO) (circle one)

{If **yes**, it's a 100% repack - then product chemistry, acute toxicity and efficacy data are not required}

Data on Group and A and B must be submitted - Group A and B can not be cited.

Guideline No.	Group A: Product Chemistry Data Study Title	Data submitted	
		Yes	No
830.1550	Product Identity & Composition	X	
830.1600	Description of materials used to produce the product	X	
830.1650	Description of formulation process		X
830.1670	Discussion on the formation of impurities	X	
830.1700	Preliminary analysis	X	
830.1750	Certified limits (158.345)	X	
830.1800	Enforcement analytical method	X	

NR

Guideline No.	Group B: Product Chemistry Data Study Title	Data submitted	
		Yes	No
830.6302	Color	X	
830.6303	Physical State	X	
830.6304	Odor	X	
830.6314	Oxidation/Reduction (Chemical incompatibility)	X	
830.6315	Flammability		X
830.6316	Explodability		X
830.6317	Storage stability		X
830.6319	Miscibility		X
830.6320	Corrosion Characteristics		X
830.6321	Dielectric Breakdown voltage		X
830.7000	pH	X	
830.7100	Viscosity		X
830.7300	Density	X	

waiver

waiver

in progress

NR

in progress

NR

NR

**21-Day Screen Completed by**  
**Contractor**

**21-Day Expires on** 4-6-11

**Jacket #** 9468-UL

**MRID#** 484205

**Content Screen:** Recommend to **Pass/Fail**

**86-5 Review:** **Pass/Fail/NA**

**Overall Status:** Recommend to **Pass/Fail**

**Transfer This Jacket to:**

Stephen Schable

PM 23



# PRIA 2 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

21 Day Screen Start Date: 3-16-11 <sup>3/23/09</sup>

Experts In-Processing Signature: B. R. Date 3-18-11 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date \_\_\_\_\_

EPA Reg. Number: <u>9468-UL</u>		EPA Receipt Date: <u>3-16-11</u>				
Items for Review				Yes	No	N/A*
1	Application Form (EPA Form 8570-1)(link to form) signed & complete including package type			X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4) (Link to form)			X		
	a) All inerts (link to <a href="http://www.epa.gov/opprd001/inerts/">http://www.epa.gov/opprd001/inerts/</a> ), including fragrances, approved for the proposed uses (see Footnote A)	yes	no			
	No inerts					
3	Certification with Respect to Citation of Data (EPA Form 8570-34) (Link to form) completed and signed (N/A if 100% repack)			X		
	Certificate and data matrix consistent			X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					
4	Formulator's Exemption Statement (EPA Form 8570-27) (Link to form) completed and signed (N/A if source is unregistered or applicant owns the technical)					X
5	Data Matrix (EPA Form 8570-35) (Link to form) both internal and external copies (PR 98-5) (Link to PR 98-5) completed and signed (N/A if 100% repack)			X		
	a) Selective Method (Fee category experts use)	yes	no			
		X				
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (link to <a href="http://www.epa.gov/oppfead1/labeling/lrm/">http://www.epa.gov/oppfead1/labeling/lrm/</a> ) (Electronic labels on CD are encouraged and guidance is available)( link to <a href="http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels">http://www.epa.gov/pesticides/regulating/registering/submissions/index.htm#labels</a> )			X		

7	Is the data package consistent with PR Notice 86-5 (link to PRN 86-5)	X		
8	Notice of Filing (link to <a href="http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm">http://www.epa.gov/pesticides/regulating/tolerance_petitions.htm</a> ) included with petitions (link to <a href="http://www.epa.gov/pesticides/regulating/tolerances.htm">http://www.epa.gov/pesticides/regulating/tolerances.htm</a> )			X
9	If applicable for conventional applications, reduced risk rationale (link to <a href="http://www.epa.gov/opprd001/workplan/reducedrisk.html">http://www.epa.gov/opprd001/workplan/reducedrisk.html</a> )			X
10	Required Data (link to <a href="http://www.epa.gov/pesticides/regulating/data_requirements.htm">http://www.epa.gov/pesticides/regulating/data_requirements.htm</a> ) and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

**Comments:**

- \* No inerts for review. Active & impurities only.
- \* In Study #1, pg 49 was missing and pages 134 & 135 were missing data. The registrant sent the corrected pages when contacted. Thus all the studies submitted along with this submission has passed the PRN 86-5 Review.

Studies passed  
Label passed

AB

MRID : 484205

\* N/A – Not Applicable

**Footnotes**

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses. If an unapproved inert is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses **even if a product is currently registered** by consulting the inert Web

site [link to <http://www.epa.gov/opprd001/inerts/lists.html>] and if the inert is not approved, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at [inertsbranch@epa.gov](mailto:inertsbranch@epa.gov) and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the Chief of Microbial Pesticides Branch [Link to [http://www.epa.gov/opbpbpd1/biopesticides/contacts\\_bppd.htm](http://www.epa.gov/opbpbpd1/biopesticides/contacts_bppd.htm)].

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information [link to <http://www.epa.gov/opprd001/inerts/tips.pdf>] must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

### **Unapproved Inerts Identified on CSFs**

#### **All applications except conventional new products and PIPs**

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;



3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

#### Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R311, R312 or R313), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

#### PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



**RE: Submission to EPA: Product Ritter Dicamba Technical (EPA Reg# 9468-UL)**

Ann Tillman to: Aswathy Balan

03/21/2011 02:29 PM

Aswathy, that is fine. I will make a note that you made that change.

Ann

-----Original Message-----

From: Balan.Aswathy@epamail.epa.gov [mailto:Balan.Aswathy@epamail.epa.gov]

Sent: Monday, March 21, 2011 2:24 PM

To: Ann Tillman

Subject: RE: Submission to EPA: Product Ritter Dicamba Technical (EPA Reg# 9468-UL)

Ms. Ann, I am putting an "Intentionally left blank" page as page number 134 and the MSDS you sent me will be pages 135-139 so that the page count of your study will not be altered and remain as 139 pages in confidential attachment. Let me know whether this is okay with you.

Aswathy Balan  
Macfadden, EPA Contractor  
2777 S. Crystal Drive, S4810  
Arlington, VA 22202  
Ph: 703-347-8787  
Fax: 703-305-5060

From: Ann Tillman <Ann@PyxisRC.com>  
To: Aswathy Balan/DC/USEPA/US@EPA  
Cc: Sree Nair/DC/USEPA/US@EPA  
Date: 03/21/2011 01:58 PM  
Subject: RE: Submission to EPA: Product Ritter Dicamba Technical (EPA Reg# 9468-UL)

Aswathy,

Attached is page 49 from Volume 1. I checked pages 134 and 135 and I realized that there must have been an error in the copy/paste when I inserted the MSDS into the original Word document and I did not catch that in the final version of the report. The information on pages 135 and 136 should have been on page 134 but somehow the information was separated. The information for Section 1 of the MSDS is found on page 136 beginning with the Company Identification. A copy of the MSDS is attached so you can see that no information is missing.

Ann

-----Original Message-----

From: Balan.Aswathy@epamail.epa.gov [mailto:Balan.Aswathy@epamail.epa.gov]

Sent: Monday, March 21, 2011 1:27 PM

To: Ann Tillman

Cc: Nair.Sree@epamail.epa.gov

Subject: Submission to EPA: Product Ritter Dicamba Technical (EPA Reg#

9468-UL)

Dear Ms. Tillman,

This is a follow-up email regarding your Application for Registration of the product Ritter Dicamba Technical (EPA Reg# 9468-UL). We have found some issues regarding your application.

In Study #1: From the confidential attachment page 49 is missing and data is missing from pages 134 and 135(these pages look incomplete).

You can send the corrected pages either by fax to 703-305-5060, Attn: Aswathy Balan or email to [balan.aswathy@epa.gov](mailto:balan.aswathy@epa.gov). Please call me back at 703-347-8787 if you have any questions.

Thanks,

Aswathy Balan  
Macfadden, EPA Contractor  
2777 S. Crystal Drive, S4810  
Arlington, VA 22202  
Ph: 703-347-8787  
Fax: 703-305-5060

[attachment "20110311 Ritter Dicamba Tech Application Package Vol. 1\_missing page.pdf" deleted by Aswathy Balan/DC/USEPA/US] [attachment "MSDS for [REDACTED].pdf" deleted by Aswathy Balan/DC/USEPA/US]

\*Manufacturing process information may be entitled to confidential treatment\*





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

March 21, 2011

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

JANELLE KAY  
PYXIS REGULATORY CONSULTING, INC.  
RITTER CHEMICAL, LLC  
4110 136TH STREET, N.W,  
GIG HARBOR, WA 98332-

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 16-MAR-11. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

March 17, 2011

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

OPP Decision Number: D-446591  
EPA File Symbol or Registration Number: 9468-UL  
Product Name: RITTER DICAMBA TECHNICAL  
EPA Receipt Date: 16-Mar-2011  
EPA Company Number: 9468  
Company Name: RITTER CHEMICAL, LLC

JANELLE KAY  
PYXIS REGULATORY CONSULTING, INC.  
RITTER CHEMICAL, LLC  
4110 136TH STREET, N.W,  
GIG HARBOR, WA 98332-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R300

NEW PRODUCT;ME-TOO PRODUCT FAST TRACK;

No additional payment is due at this time. We will process a refund of your \$3,373 overpayment as soon as is practicable.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-9362.

Sincerely, *Teresa Downs*  
Front End Processing Staff  
Information Technology & Resources Management Division

**Fee for Service**

*M*  
{892170É~

This package includes the following

- ☒ New Registration
- ☐ Amendment

- ☒ Studies?      ☐ Fee Waiver?  
☐ volpay    % Reduction: \_\_\_\_

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 23

Receipt No.

S-

892170

EPA File Symbol/Reg. No.

9468-UL

Pin-Punch Date:

3/16/2011

☐ This item is NOT subject to FFS action.

Action Code:

Requested:

R310

Granted:

R300

Amount Due: \$ 1434<sup>00</sup>

Parent/Child Decisions:

*Active & impurities only. AB 03/18/11*

☒ Inert Cleared for Intended Use



Uncleared Inert in Product

Reviewer: *[Signature]*

Date: 3/17/11

Remarks:

Sarah Greubel

---

From: paygovadmin@mail.doc.twai.gov  
Sent: Monday, March 14, 2011 3:06 PM  
To: Sarah Greubel  
Subject: Pay.Gov Payment Confirmation

THIS IS AN AUTOMATED MESSAGE. PLEASE DO NOT REPLY.

Your transaction has been successfully completed.

Transaction Summary

Application Name: PRIA Service Fees  
Pay.gov Tracking ID: 252R8C4L  
Agency Tracking ID: 74183880854  
Transaction Type: Sale  
Transaction Date: Mar 14, 2011 6:05:31 PM

Account Holder Name: Ann Tillman  
Transaction Amount: \$4,807.00  
Billing Address: 4110 136th St NW  
City: Gig Harbor  
State/Province: WA  
Zip/Postal Code: 98332  
Country: USA  
Card Type: AmericanExpress  
Card Number: \*\*\*\*\*1031

Decision Number:  
Registration Number:  
Company Name: Ritter Chemical LLC  
Company Number: 9468  
Action Code: R310





9468-UL

E300

## **Memorandum**

Needs  
Admin

KM

3/22

Date: 03 / 22 / 11

To: PM 23, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

**We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.**

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:

- ☒ fully accepted submission
- ☐ partially accepted submission
- ☐ rejected submission

PYXIS REGULATORY CONSULTING, INC.

484205-00

4110 136<sup>th</sup> St. NW  
Gig Harbor, WA 98332

Phone: 253-853-7369  
Fax: 253-853-5516  
www.PyxisRC.com

March 11, 2011

OVERNIGHT DELIVERY

Kathryn Montague (PM 23)  
Document Processing Desk (REGFEE)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202

RE: Ritter Chemical, LLC  
Ritter Dicamba Technical (EPA File Symbol 9468- )  
Application for New Pesticide Registration  
PRIA category R310 (46: New manufacturing use product)

Dear Ms. Montague,

On behalf of Ritter Chemical, LLC, we are submitting an application for registration of Ritter Dicamba Technical. In support of this application, we submit the following documents:

1. Application for a New Pesticide Registration (EPA Form 8570-1)
2. Confidential Statement of Formula (EPA Form 8570-4)
3. Three (3) Copies of the Proposed Labeling
4. A CD containing an electronic version of the proposed labeling
5. Certification with Respect to Label Integrity
6. Certification with Respect to Citation of Data (EPA Form 8570-34)
7. Agency Internal Use Copy of the Data Matrix
8. Public File Copy of the Data Matrix
9. Copy of PRIA payment
10. Letter of Authorization
11. Product Specific Data (3 copies of each report):

48420501

Volume 1	830.1550, 830.1600, 830.1620, 830.1650, 830.1670, 830.1750, 830.1800	Tillman, A. M. Product Identity and Composition, Description of the Materials Used, Description of the Production Process, Description of the Formulation Process, Discussion of the Formation of Impurities, Certified Limits, and Enforcement Analytical Method for Ritter Dicamba Technical. <i>Contains Confidential Business Information.</i>
Volume 2	830.1700, 830.1800	Li, H. Preliminary Analysis and Enforcement Analytical Method of Dicamba TGAI. <i>Contains Confidential Business Information.</i>

48420502

<b>48420503</b>	Volume 3	830.6302, 830.6303, 830.6304, 830.6313, 830.6314, 830.7000, 830.7050, 830.7200, 830.7300	Weller, P. J. Group B Product Chemistry Analysis of Dicamba Technical.
<b>48420504</b>	Volume 4	830.6313, 830.6315, 830.6316, 830.6317, 830.6319, 830.6320, 830.6321, 830.7100, 830.7220, 830.7300, 830.7370, 830.7520, 830.7550-7570, 830.7840-7860, 830.7950	Tillman, A. M. Ritter Dicamba Technical Waiver Requests for Certain Phys-Chem Properties.

We would like to note that Ritter Chemical, LLC is using the cite-all method of support. As per EPA's interpretations of 40 CFR Parts 152.86(b)(2)(i) and 152.93(b)(2)(i), Ritter Chemical, LLC submitted notices of intent to apply and offers to pay to all companies on the September 30, 2010 Data Submitter's List. This action falls under PRIA category R310 (46: New manufacturing use product) because it is an application for registration for a manufacturing use product identical to a currently registered product. The PRIA fee for this action is \$4,807 and has been paid. The decision timeline is 6 months.

We trust you will find this application complete. However, please feel free to contact me ((253) 853-7369, [Ann@PyxisRC.com](mailto:Ann@PyxisRC.com)) if you have any questions or need any additional information.

Sincerely,



Ann M. Tillman

Enclosures

# Certification with Respect to Label Integrity

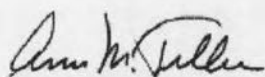
version: 9/11/02

I certify that the information (including, but not limited to, text, tables, and graphics) contained in the electronic file identified below by file name and submitted with this certification is the same information as that on the paper copies of these documents included with this submission.

## PROPOSED LABEL

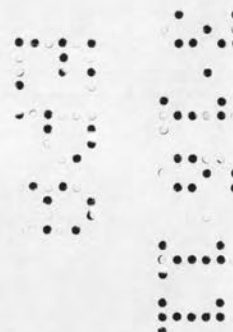
EPA Registration #	Date Submitted to EPA	Electronic file name
009468-xxxxx	March 11, 2011	009468-xxxxx.20110311.Ritter Dicamba Technical label.v1.pdf

I certify that the statements that I have made on this form are true, accurate, and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.



Signature  
Ann M. Tillman  
Consultant, Ritter Chemical, LLC

March 11, 2011  
Date







**Ritter Chemical LLC**

October 28, 2009

To Whom It May Concern:

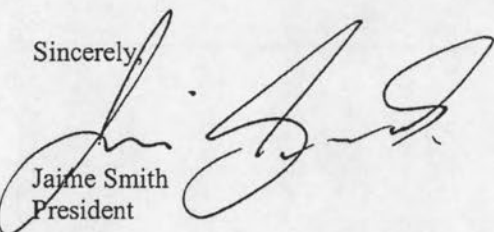
RE: Letter of Authorization

Dear Sir or Madam:

Please let this letter serve to confirm that Pyxis Regulatory Consulting, Inc. is authorized to act as agents for Ritter Chemical, LLC (EPA Company Number 9468), before the U.S. Environmental Protection Agency and state governmental agencies in all matters regarding our pesticide registrations pursuant to the Federal Insecticide, Fungicide and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136 et seq. and state law.

If you have any questions, please do not hesitate to contact me.

Sincerely,



Jaime Smith  
President

cc: Pyxis Regulatory Consulting, Inc.

Ritter Dicamba Technical  
Ann Tillman  
to:  
Akiva Abramovitch  
09/06/2011 01:24 PM  
Show Details

Akiva,



Ann

*Ann M. Tillman, Ph.D.  
Pyxis Regulatory Consulting, Inc.  
4110 136<sup>th</sup> St. NW  
Gig Harbor, WA 98332  
Office (253) 853-7369  
Fax (253) 853-5516  
Email Ann@PyxisRC.com*

\*Manufacturing process information may be entitled to confidential treatment\*









